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Notes

Science Misconduct and Due Process: A Case of Process Due

by
ELIZABETH HOWARD*

Academic fraud is a threat to the intellectual integrity on which the advancement of knowledge depends.¹

Introduction

The National Academy of Sciences (NAS) states that “the community of scientists [is bound by an honor system based on] truthfulness, both as a moral imperative and as a fundamental operational principle in the scientific research process.”² Because of the importance of the honor system and the severe consequences that result from breaching it, science misconduct has been the focus of debate and study by individual scientists, legal scholars, professional societies, government agencies, and research institutions.³ In the last decade,

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1. Richard A. Epstein, *The Morality of Scientists: On Drafting Rules and Procedures for Academic Fraud*, 24 MINERVA 344, 347 (1986).

2. PANEL ON SCIENTIFIC RESPONSIBILITY AND THE CONDUCT OF RESEARCH, COMMITTEE ON SCIENCE, ENGINEERING, AND PUBLIC POLICY, NATIONAL ACADEMY OF SCIENCES, NATIONAL ACADEMY OF ENGINEERING, INSTITUTE OF MEDICINE, RESPONSIBLE SCIENCE: ENSURING THE INTEGRITY OF THE RESEARCH PROCESS 17 (1992) [hereinafter NAS PANEL].

3. See generally WILLIAM BROAD & NICHOLAS WADE, BETRAYERS OF THE TRUTH (1982) (presenting case histories of fraudulent scientists and analysis of underlying causes of the misconduct); JAN SAPP, WHERE THE TRUTH LIES: FRANZ MOEWUS AND THE ORIGINS OF MOLECULAR BIOLOGY (1990) (exploring contributing factors to research misconduct). For more extensive discussions of institutional and federal policies regarding misconduct, see AAAS-ABA NATIONAL CONFERENCE OF LAWYERS AND SCIENTISTS,

highly publicized misconduct cases have called the integrity of this honor system into question.⁴ These high-profile cases have both seriously undermined public confidence in science research and highlighted the importance of finding a solution to the problem of science misconduct.

A charge of misconduct endangers the reputation and grant-obtaining ability of the professional scientist. Subjecting a scientist to misconduct proceedings without the benefit of due process protections both violates her constitutional rights and runs directly counter to the public interest. Due process protections must be provided to minimize the chilling effect of misconduct regulations on a scientist's willingness to pursue experimental research, and to maximize the ability of a fact-finding body to determine whether research is fraudulent, including that research underlying the development of critical pharmaceuticals.

Science misconduct has important consequences both for the individuals accused of misconduct and for society as a whole. The ramifications of a finding of misconduct are enormous for the individual involved. In academic science, the loss of reputation and trustworthiness can be career-ending. Furthermore, for science to progress scientists must be able to trust data on which new theories and experiments are based. Many commentators have argued that in science bad results are usually detected because published results can always be repeated by others in the field.⁵ Others dispute the likelihood that experiments will be repeated because a premium is placed on original research. Thus, replicating published experiments reaps little or no reward.⁶ Further, if scientists did have to repeat all the past experiments underlying their own research, they would risk spending their careers "reinventing the wheel," gravely slowing down the rate at which science progresses. Because of the premium placed on professional reputation, a scientist who has, for example, been found guilty of deliberate misrepresentation of scientific data will have difficulty

PROJECT ON SCIENTIFIC FRAUD AND MISCONDUCT: REPORT ON WORKSHOP NUMBER ONE, September 18-20, 1987 [hereinafter AAAS-ABA CONFERENCE]; NAS PANEL, *supra* note 2.

4. See, e.g., David L. Wheeler, *U.S. Has Barred Grants to 6 Scientists in Past 2 Years*, CHRON. HIGHER EDUC., July 3, 1991, at A1 (summarizing conduct cases resolved by the Public Health Service from March 1989 to March 1991). For more extensive case histories of recent and historical incidents of misconduct, see BROAD & WADE, *supra* note 3; SAPP, *supra* note 3.

5. See *Fraud in Biomedical Research: Hearings Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 97th Cong., 1st Sess. 66 (1981) (statement of Dr. Phillip Handler, President, National Academy of Arts and Sciences) [hereinafter *Hearings*]; see also BROAD & WADE, *supra* note 3, at 61 (detailing parallel positions taken by various other scientists in the field).

6. See SAPP, *supra* note 3, at 23 and references therein.

regaining the trust she has violated. In addition to the private interests at stake, the government has a considerable interest in ensuring the integrity of the scientific community on which the health of its citizens and so much of the country's industrial base depends.

Given government and society's interests, the process by which misconduct is uncovered is as important as the result. Fact-finding procedures must be accurate and must not deter scientists from pursuing beneficial research. Current models for addressing misconduct do not provide adequate due process protections, and therefore meet neither of these aims.

In the unique setting of scientific research, the need for due process is pressing. Due process protections will enhance the fact-finding capability of the misconduct proceeding and will ensure the fairest setting for the researcher to present her case. The difficulty in distinguishing error from fraud in scientific research makes the fact-finding aspect of the proceeding especially critical. Innocent errors in research are common consequences of the creative pursuit of scientific truths. If researchers believe such errors will precipitate proceedings in which they will not be treated fairly, they may abandon their research altogether.⁷

Two prominent recent incidents demonstrate the deficiencies of past efforts to deal with the problem of science misconduct: the cases of Dr. David Baltimore and Dr. Robert Gallo. In each case allegations of misconduct were dealt with through a series of investigations that stretched out over a period of years, often employing different standards against which to judge misconduct. The lack of a consistent standard of misconduct violates the due process requirement of notice, in that scientists do not know how to conform their conduct to constantly shifting criteria.

Dr. Baltimore, a Nobel laureate, became embroiled in a misconduct controversy following the publication of a research paper in April 1986.⁸ The "April *Cell* paper" was a collaborative effort between two different laboratories at the Massachusetts Institute of Technology (MIT), one run by Dr. Baltimore and the other by Dr. Thereza Imanishi-Kari. The paper represented an important contribution to the understanding of mechanisms underlying regulation of the human immune system. Although she had not participated in the research for the paper, Dr. Margot O'Toole, a postdoctoral researcher in Dr. Imanishi-Kari's lab, questioned the validity of Imanishi-Kari's

7. See *infra* note 92.

8. David Weaver et al., *Altered Repertoire of Endogenous Immunoglobulin Gene Expression in Transgenic Mice Containing a Rearranged Mu Heavy Chain Gene*, 45 *CELL* 247 (1986).

research data.⁹ Dr. O'Toole's charges were considered in two reviews conducted by Tufts University,¹⁰ which was considering Dr. Imanishi-Kari for a faculty appointment at that time. These review panels concluded that "O'Toole's complaints involved matters of interpretation,"¹¹ and recommended no corrective action. Dr. O'Toole then took her charges to MIT, which appointed a single individual, Professor Herman Eisen, to review them. Professor Eisen concurred with the conclusions of the Tufts University panels.¹²

A second researcher, Dr. Charles Maplethorpe, who formerly worked in Dr. Imanishi-Kari's laboratory and who also was uninvolved with the paper under dispute, contacted Walter Stewart and Ned Feder at the National Institutes of Health (NIH), both of whom had established reputations as investigators of scientific fraud.¹³ Based on conversations with Drs. Maplethorpe and O'Toole and on copies of seventeen pages of Dr. Imanishi-Kari's notebook provided by Dr. O'Toole, Stewart and Feder "wrote a lengthy manuscript clearly charging that [the April *Cell*] paper was consciously misleading."¹⁴ After they failed to find a publisher for their manuscript, Stewart and Feder "circulated the manuscript widely to scientists" and "began speaking about their 'investigation' on university campuses and at scientific meetings."¹⁵

In 1988, Dr. Baltimore learned from a newspaper reporter that allegations of his misconduct would shortly be the subject of two congressional investigations.¹⁶ On behalf of Dr. Imanishi-Kari and himself, Dr. Baltimore maintained that "[w]e were not notified of these

9. See David Baltimore, *Baltimore's Travels*, ISSUES IN SCI. & TECH., Summer 1989, at 48, 49.

10. The two reviews were conducted by a special panel considering the suitability of Dr. Imanishi-Kari for a faculty appointment and by a scientific review panel. *Id.* at 49.

11. *Id.*

12. *Id.*

13. The NIH recently shut down the fraud-detecting efforts of Drs. Stewart and Feder, in part because their investigations had expanded to cover acts of non-scientists receiving no funding from the NIH. Philip J. Hilts, *Institutes of Health Close Fraud Investigation Unit*, N.Y. TIMES, May 5, 1993, at A21. The ex-investigators were transferred to new positions within the NIH, told to discontinue their probes, and denied access to their files. *Id.* For two very different assessments of this decision, see Anthony Flint, *High Tech Blurs Boundaries of Plagiarism*, BOSTON GLOBE, Sept. 26, 1993, at 1 (applauding the decision), and Jerry Seper, *Hill Aides Meet GAO Probers in Transfer of Whistleblowers*, WASH. TIMES, Oct. 19, 1993, at A9 (criticizing the action).

14. Baltimore, *supra* note 9, at 50.

15. *Id.*

16. The investigations were to be conducted by the Oversight and Investigations Subcommittee of the House Energy and Commerce Committee, and the Human Resources and Intergovernmental Relations Subcommittee of the House Government Operations Committee. Baltimore, *supra* note 9, at 50.

hearings nor were we permitted to answer the charges against us.”¹⁷ Before these hearings, Dr. Baltimore wrote letters to about 400 colleagues, “acquainting them with [his] side of this matter.”¹⁸ The letter-writing campaign was sharply criticized as an inappropriate attempt to influence the fact-finding process and was widely viewed as damaging to Dr. Baltimore’s position.¹⁹

At the same time as the congressional investigation, the NIH was conducting an independent investigation at Dr. Baltimore’s request. The latter investigation concluded first and found all concerned innocent of any wrongdoing.²⁰ Meanwhile, at the request of one of the congressional committees, Dr. Imanishi-Kari’s notebooks were being examined by the Secret Service’s forensic experts. The Secret Service concluded that “[a]pproximately 20 percent of the data . . . were faked, and key printouts of data that Imanishi-Kari said had been produced in 1985 when she was working on her paper actually came from someone else’s research in the early 1980s.”²¹

Largely on the basis of these findings, a second NIH investigation stated in a draft report that Dr. Imanishi-Kari had “‘repeatedly presented false and misleading information to the NIH’ and ‘falsified’ a ‘substantial’ portion of her laboratory work.”²² While the NIH report did not find Dr. Baltimore personally guilty of misconduct, “it said that his persistent defense of the paper was ‘deeply troubling.’”²³ Over the course of these investigations, Dr. Imanishi-Kari, who is still the subject of an NIH ethics investigation, lost her federal funding and Dr. Baltimore was effectively forced to resign as president of Rockefeller University.

Dr. Imanishi-Kari’s alleged falsification of data was referred to the United States Attorney’s office for possible criminal charges. In late spring of 1992, Dr. Imanishi-Kari’s lawyers received, for the first time, a copy of the forensic analysis undertaken by the Secret Service. This data was submitted to an independent forensic analyst, resulting in a report highly critical of the Secret Service analysis. On July 13,

17. *Id.*

18. *Id.* at 51.

19. See Wade Roush, *John Dingell: Dark Knight of Science*, 95 *TECH. REV.* 56, 62 (1992) (reporting that a staff member on the NAS Panel, David Guston, regarded the “Dear Colleague” letter to be “an example of senseless brinkmanship,” and stating the report concluded that Baltimore’s actions in defending Imanishi-Kari “stained his credibility”).

20. John Crewdson, *Burden of Proof: Gallo Case Spotlights a Key Question: Can U.S. Science Be Believed?*, *CHI. TRIB.*, Dec. 6, 1992, at C1 [hereinafter Crewdson, *Burden of Proof*].

21. Malcolm Gladwell, *Prosecutors Halt Scientific Fraud Probe; Researcher Baltimore Claims Vindication, Plans to ‘Unretract’ Paper*, *WASH. POST*, July 14, 1992, at A3.

22. *Id.*

23. *Id.*

1992, the federal prosecutors said they would drop their investigation. Dr. Baltimore's response: "I feel vindicated."²⁴ Dr. Imanishi-Kari's attorney said the new evidence "demonstrates that there has been no fraud,"²⁵ but the United States Attorney handling the case said that "the decision of his office should not be taken as 'a certification of any research conducted by Imanishi-Kari.'"²⁶

The case of Dr. Robert Gallo, a researcher at the NIH,²⁷ also illustrates the difficulties inherent in misconduct investigations. Dr. Gallo was the first to report the discovery of the AIDS virus.²⁸ This announcement had been preceded, however, by a report by Dr. Luc Montagnier, a French scientist, about a virus that he called LAV which he speculated might be the cause of AIDS.²⁹

A series of articles in the *Chicago Tribune*³⁰ precipitated a controversy in the science community and the public at large over whether the virus isolated by Dr. Gallo, HTLV-III, was in fact the same virus reported by Dr. Montagnier. Dr. Montagnier had provided the Gallo lab with an isolate of LAV before publication of Dr. Gallo's 1984 *Science* paper. The *Tribune* alleged that Dr. Gallo's virus culture had been contaminated by Dr. Montagnier's virus isolate through carelessness, or perhaps through intentional manipulation.³¹

In late 1990, the Office of Science Integrity (OSI), a branch of the NIH, began a full-scale investigation of the allegations of misconduct on the part of Dr. Gallo. The final report issued by OSI in late 1991 found that Dr. Gallo was innocent of sixteen charges of misconduct.³² These results were sharply criticized by the Richards panel, a panel convened by the NAS and the Institute of Medicine to "monitor the investigation."³³ The Richards panel disagreed with the conclusions of the OSI report and argued that "[t]he conclusion section . . . fails to integrate the findings into a larger context, namely a *pattern* of behav-

24. Gladwell, *supra* note 21.

25. *Id.*

26. *Id.*

27. See Philip J. Hilts, *Federal Inquiry Finds Misconduct By a Discoverer of the AIDS Virus*, N.Y. TIMES, Dec. 31, 1992, at A1 [hereinafter Hilts, *Federal Inquiry Finds Misconduct*].

28. See Robert C. Gallo et al., *Frequent Detection and Isolation of Cytopathic Retroviruses (HTLV-III) from Patients with AIDS and at Risk for AIDS*, 224 SCIENCE 500 (1984).

29. See F. Barré-Sinoussi et al., *Isolation of a T-Lymphotropic Retrovirus from a Patient at Risk for Acquired Immune Deficiency Syndrome (AIDS)*, 220 SCIENCE 868 (1983).

30. E.g., John Crewdson, *The Great AIDS Quest*, CHI. TRIB., Nov. 19, 1989, § 5, at 1.

31. In May 1991, Dr. Gallo formally conceded that the virus which he reported to be the AIDS virus was probably a contaminant of the virus provided to his lab by Dr. Montagnier. Hilts, *Federal Inquiry Finds Misconduct*, *supra* note 27, at A11.

32. Joseph Palca, *'Verdicts' Are in on the Gallo Probe*, 256 SCIENCE 735, 735 (1992).

33. David P. Hamilton, *Scientist-Consultants Accuse OSI of Missing the Pattern*, 256 SCIENCE 738, 738 (1992).

ior on Dr. Gallo's part that repeatedly misrepresents, suppresses, and distorts data and their interpretation."³⁴ The Richards panel characterized Dr. Gallo's conduct as "intellectual recklessness of a high degree—in essence, *intellectual appropriation* of the French viral isolate."³⁵

Unfortunately for Dr. Gallo, his troubles did not end with the OSI report. In December 1992, three years after allegations of his misconduct first surfaced, the Office of Research Integrity (ORI)³⁶ of the Department of Health and Human Services (DHHS) found Dr. Gallo guilty on four counts of scientific misconduct. The report concluded that "Dr. Gallo had intentionally misled colleagues to gain credit for himself and diminish credit due his French competitors." Furthermore, Dr. Gallo's false statement³⁷ had "impeded potential AIDS research progress" by retarding collaborations with Dr. Montagnier's group.³⁸ Following the ORI report, Dr. Gallo elected to pursue an administrative hearing with the Appeals Board of the DHHS.³⁹ On November 12, 1993, only three days before the hearings were to begin, the ORI announced it would drop all charges against Dr. Gallo because it did not believe it could meet the "new, more stringent standards for what constitutes misconduct."⁴⁰ Echoing

34. *Id.* at 739.

35. *Id.* at 738.

36. The Office of Research Integrity (ORI) was created in 1992. It replaced and superseded the OSI and OSIR. See *infra* text accompanying note 111.

37. A key point of contention in the Gallo dispute was whether Gallo's laboratory had succeeded in culturing LAV. In refuting claims that the Gallo isolate was actually a contaminant from the LAV received from Montagnier, Gallo said that "it would have been 'physically impossible' for the French virus to have contaminated Gallo's cultures [since Gallo had never succeeded in culturing LAV and 'to have contamination one must have growth']." The *Chicago Tribune*, however, found by examining notebooks and other documents from the Gallo lab that LAV had been successfully grown there for months. This finding has now been accepted by NIH investigators of the case. Crewdson, *Burden of Proof*, *supra* note 20.

38. Hilts, *Federal Inquiry Finds Misconduct*, *supra* note 27.

39. Telephone Interview with Dr. Lyle W. Bivens, Director, Division of Policy and Education, Office of Research Integrity (Jan. 6, 1993).

40. Philip J. Hilts, *Misconduct Charges Dropped Against AIDS Virus Scientist*, N.Y. TIMES, Nov. 13, 1993, at A1 [hereinafter Hilts, *Misconduct Charges Dropped*]. The ORI is bound by the decisions of the Department Appeals Board (DAB), which has recently declared a new standard of proof for findings of misconduct:

[T]he ORI must now prove "deliberate intent to deceive" on the part of the scientist it says is responsible for a false statement, and that false statement [must have] a "material or significant effect on the research conclusions of the paper."

There can also be "no possibility of honest error."

John Crewdson, *When Scientists, Lawyers Argue, Justice is the Loser*, CHI. TRIB., Nov. 14, 1993, at C1. Dr. Lyle Bivens explained the ORI's decision by stating, "ORI maintains that the standards applied by the [DAB] reflect a fundamental disagreement with ORI as to the importance of clarity, accuracy, and honesty in science. However, because ORI is bound

Dr. Baltimore's comment, Dr. Gallo reacted to the news by commenting, "I have been completely vindicated."⁴¹ Dr. Gallo still faces charges of perjury and patent fraud (for the AIDS blood test) brought by a House subcommittee.⁴²

The Gallo and Baltimore cases raise many issues. What constitutes misconduct? Does failure to verify the data of a co-author, as Baltimore was alleged to have done, constitute misconduct? Does intellectual appropriation? Taking credit for the work of others? Furthermore, what access to evidence should be allowed? Should each side of the dispute have access to the evidence used by the fact-finders? Who is better suited to determine misconduct—the scientist or the lawyer? Does an adversarial system achieve the best balance of exposing misconduct while allaying researchers' fears of being falsely found guilty of misconduct? Or is the scientific community better suited to deal with these issues internally by less formal means?

The resolution of these issues hinges, in part, on the degree of due process to which the misconductee is entitled. A definition of misconduct, for example, should include a provision for notice, which is a component of due process both as to when investigatory or adjudicatory proceedings are commenced against them and also as to what norms they are expected to conform.⁴³ Individuals must be aware of what constitutes good conduct before sanctions for *misconduct* are fair and comport with due process.

Part I of this Note discusses past efforts to develop a definition of science misconduct and examines the pervasiveness of science misconduct.⁴⁴ Part II covers current methods of dealing with allegations of misconduct at the institutional and administrative agency level, focusing primarily on the approaches followed by the NIH and the National Science Foundation (NSF), which are the major funding agencies in

by the [DAB's] decisions, it will not continue its proceedings against Dr. Gallo." Hilts, *Misconduct Charges Dropped*, *supra*.

41. Hilts, *Misconduct Charges Dropped*, *supra* note 40.

42. Hilts, *Federal Inquiry Finds Misconduct*, *supra* note 27, at A11. When Montagnier supplied LAV to Gallo, it was with the understanding that the virus was not to be used for commercial purposes. If the Gallo virus is indeed LAV, the patent obtained with the virus violates this agreement. The Presidents of the United States and France agreed that Montagnier and Gallo would split the royalties from the patent. *Id.* Gallo himself receives \$100,000/year from this patent. Crewdson, *Burden of Proof*, *supra* note 20.

43. See *infra* text accompanying notes 233-236 for a discussion of the procedural elements of due process.

44. This Note focuses primarily on allegations of science misconduct in the biomedical field. Ninety percent of the recent public instances of research misconduct have occurred in this field. Allan Mazur, *Allegations of Dishonesty in Research and Their Treatment by American University*, 27 MINERVA 177, 178 (1989). The general principles outlined in this Note are, however, not particular to the biomedical field and should be equally applicable to other scientific research fields.

the biomedical field that have developed policies for handling allegations of science misconduct.⁴⁵

Part III identifies what due process protections are necessary for these investigations. An alleged misconductee is entitled to due process because of the enormous professional ramifications of such an allegation. Furthermore, misconductees are entitled to that protection in full measure. The private interest affected by official actions is particularly weighty in these cases because professional careers are at stake, and the risk of error in the investigations is high given the complex nature of the evidence. Furthermore, the administrative and fiscal burdens of due process protections are outweighed by the government interest in maximizing the reliability of scientific research, including the avoidance of fraudulent patent claims.

Part IV proposes a model procedure for dealing with allegations of misconduct that places responsibility for conducting misconduct proceedings with an independent federal board established for the purpose of investigating allegations of misconduct. The misconduct proceedings would be "quasi-judicial" in nature, providing "trial-type" protections to the accused, including representation of counsel, confrontation and cross-examination of witnesses, and the use of formal evidentiary rules.

Misconduct in science must be confronted, clear guidelines must be provided, and regulations must be enforced. If adequate due process protections are not provided, guidelines and regulations will have a chilling effect on scientific research. These measures are necessary to protect reliable data, to expose fraudulent data, and to assure the public that, among other things, pharmaceutical products are safe and effective.

I. Misconduct in Science: How Significant?

The prevalence of misconduct in science has been widely debated. Estimates of the frequency of its occurrence vary widely. At the extremes, the estimates strain credibility. One editorial statement averred that scientific literature is 99.9999 percent "pure" (*i.e.*, one paper or less per million is fraudulent);⁴⁶ other commentators maintain that for every major case of fraud that becomes public, there are 100,000 cases that go undetected.⁴⁷ Those favoring low estimates point to the relative rarity of confirmed incidences of science miscon-

45. See *infra* Part II.A-B.

46. Daniel E. Koshland, Jr., *Fraud in Science*, 235 *SCIENCE* 141 (1987).

47. BROAD & WADE, *supra* note 3, at 87 ("[F]or every case of major fraud that comes to light, a hundred or so go undetected. For each major fraud, perhaps a thousand minor fakes are perpetrated.").

duct.⁴⁸ Commentators citing higher figures argue that the incidence of science misconduct is grossly underreported.⁴⁹

The discrepancy in estimates of the prevalence of science misconduct indicates that existing procedures do not deal with the problem adequately. If scientists define misconduct differently, estimates of the incidents of misconduct will vary; if scientists lack formalized channels within which to raise their concerns, or if reports are deterred by the threat of reprisal, underreporting will result.

Despite the wide disparity in perceptions of the frequency of misconduct in science, however, few commentators⁵⁰ minimize the importance of dealing with misconduct when it occurs. A single well-publicized case of science misconduct can affect tangible necessities like tax-supported public funding. Moreover, by damaging the reputation of the scientific community, a notorious instance of misconduct can exacerbate the actual harm caused by science misconduct. The scientific community may disagree about the best method to address the problem of misconduct in science, but few disagree about the need.⁵¹

A. Scientific Misconduct Defined

The Public Health Service (PHS) and the NSF have each promulgated broad definitions of misconduct⁵² in science. The PHS defines misconduct in science as "fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or

48. See *infra* text accompanying notes 72-77.

49. See *infra* text accompanying notes 78-82.

50. See David P. Hamilton, *A Shaky Consensus on Misconduct*, 256 SCIENCE 604, 604 (1992) (stating that two noted scientists believe the importance of misconduct to overstated).

51. See, e.g., SAPP, *supra* note 3, at 8; see also *infra* note 86 and accompanying text.

52. Using the term "misconduct" rather than "fraud" has itself been a source of disagreement within the field. The Office of Management and Budget, for example, in responding to the draft DHHS rule, stated that "[w]e are concerned that your proposal goes beyond the mandate of Section 493 of the Public Health Services Act, which deals with scientific fraud, by attempting to regulate the broader area of scientific misconduct." *Government Operations, OMB Tells HHS to Revamp Proposal Governing Misconduct in Science*, DAILY REPORT FOR EXECUTIVES, THE BUREAU OF NATIONAL AFFAIRS, INC., May 6, 1988. At least one reason for the use of the term "misconduct" rather than "fraud" is to avoid confusion with the common-law tort of fraud, which requires reliance and damages before the conduct is actionable. See W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 105 (5th ed. 1984). For a more detailed discussion of the difference between fraud and misconduct, see Robert M. Andersen, *The Federal Government's Role in Regulating Misconduct in Scientific and Technological Research*, 3 J.L. & TECH. 121, 128 (1988) (arguing, for example, that "damage and reliance are inappropriate elements in a prima facie case of intentional misconduct").

reporting research.”⁵³ These guidelines exclude “honest error or honest differences in interpretations or judgments of data.”⁵⁴

The NSF defines misconduct as:

(1) [F]abrication, falsification, plagiarism, or other serious deviation from accepted practices in proposing, carrying out, or reporting results from activities funded by NSF; or (2) Retaliation of any kind against a person who reported or provided information about suspected or alleged misconduct and who has not acted in bad faith.⁵⁵

53. 42 C.F.R. § 50.102 (1992).

54. *Id.* A category that has neither been expressly included in either of the federal guidelines, nor considered by the Panel, is conflict of interest. This omission created dissension within the Panel. Two panelists, in a minority statement following the Panel's conclusions, stated that “conflicts of interest directly related to research can be more complex, potentially more serious and perhaps more numerous than the examples of fabrication, falsification, and plagiarism, and therefore need to be addressed in this report.” NAS PANEL, *supra* note 2, at 181. Conflict of interest issues arise when researchers have financial ties to the subject of their research—a situation of increasing concern in academic research, particularly in the biomedical field. For further discussion of the problem of conflicts of interest in science research, see Paul J. Friedman, *Controlling Conflict of Interest*, ISSUES IN SCI. & TECH., Fall 1991, at 60; Michael E. Gluck et al., *University-Industry Relationships in the Life Sciences: Implications for Students and Post-Doctoral Fellows*, 16 RES. POL'Y 327, 335-36 (1987); Sheldon Krinsky et al., *Academic-Corporate Ties in Biotechnology: a Quantitative Study*, SCI., TECH., & HUM. VALUES, Summer 1991, at 275. See also Ted Weiss, *Too Many Scientists Who 'Blow the Whistle' End Up Losing Their Jobs and Careers*, CHRON. HIGHER EDUC., June 26, 1991, at A36. Representative Weiss, D-N.Y., argues that “at a minimum, N.I.H.-funded scientists should be required to disclose their financial ties to such companies every time they present their research results orally or in writing.” *Id.* He emphasizes, however, that these disclosures should apply “only to researchers whose ties to industry could compromise their N.I.H.-sponsored clinical or epidemiological research. Consulting relationships with private industry on other matters would not be influenced.” *Id.* However, since this category has not been included in the federal agencies' definition of misconduct, it will not be discussed further in this Note.

55. 45 C.F.R. § 689.1 (1991). The NSF definition of misconduct is broader than that of DHHS, of which the PHS is an operating division. The NSF definition covers all “activities funded by NSF,” rather than just research as provided for in DHHS rules. 45 C.F.R. § 689.1(a)(1). In addition to research, the NSF funds science and engineering education. In responding to concerns that this definition was too broad, the NSF stated that “in many NSF activities research and education are inextricably combined. In these circumstances, the NSF must be able to ensure integrity in proposing, conducting, and reporting results from NSF-funded science and engineering education as well as research.” Misconduct in Science and Engineering, 56 Fed. Reg. 22,286 (1991). The PHS also requires institutions receiving PHS funds to have policies and procedures that provide for “undertaking diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.” 42 C.F.R. § 50.103(d)(13) (1991). In contrast to the NSF rule, the PHS rule does not provide explicit authority for “any action to be taken by PHS against someone who, while enjoying PHS financial support, retaliates against a good faith whistleblower.” Misconduct in Science and Engineering at 22,287. For a more extensive discussion of the problem of protecting whistleblowers, see PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, AAAS COMMITTEE ON SCIENTIFIC FREEDOM AND RESPONSIBILITY, WHISTLEBLOWING IN BIOMEDICAL RESEARCH: PROCEEDINGS OF A WORKSHOP (Judith P. Swazey & Stephen R.

The NSF definition of misconduct does not include "[o]rdinary errors, ordinary differences in interpretations or judgments of data, scholarly or political disagreements, personal or professional opinions, or private moral or ethical behavior or views."⁵⁶

Even though the PHS guidelines expressly exclude "honest error or honest differences in interpretations or judgments of data," it is unclear whether the misconduct must be intentional to be actionable, or whether not observing a standard of reasonable care will suffice. The Deputy General Counsel of the NSF, Robert M. Andersen,⁵⁷ states that "'scientific malpractice' is misconduct only if the actions in question constitute aggravated or gross negligence."⁵⁸ Other commentators have argued that error due to mere negligence is culpable.⁵⁹

The issue of scienter is important because the possibility of self-deception is always present in science research. As stated in one commentary:

Self-deception and outright fraud differ in volition—one is unwitting, the other deliberate. Yet it is perhaps more accurate to think of them as two extremes of a spectrum, the center of which is occupied by a range of actions in which the experimenter's motives are ambiguous, even to himself.⁶⁰

Scher eds., 1981); Harold P. Green, *Scientific Responsibility and the Law*, 20 U. MICH. J.L. REF. 1009, 1027 (1987) (urging that whistleblowers have specific protections against liability, requiring, "as a condition of employment as a research scientist, the execution of an instrument releasing from defamation liability any person who in the future makes any statements to officials of any scientific, educational, or governmental entity to the effect that the employee has engaged in scientific misconduct, unless the statements made are determined to be untrue, without any reasonable basis, and to have been made with malice").

56. Misconduct in Science and Engineering at 22,287.

57. Andersen cautions that his statements are "solely those of the author, and no official support or endorsement by the National Science Foundation is intended or should be inferred." Andersen, *supra* note 52, at 121.

58. *Id.* at 130. Andersen argues that "[i]f NSF were presented with such a case, the Foundation would use evidentiary procedures similar to those used by courts in malpractice actions to establish 'duty owed' or 'level of care' required of the supervising scientist under the circumstances. The Foundation would then be in a position to determine if a 'serious deviation from accepted practices' had occurred." *Id.* at 131.

59. See Robert L. Engler et al., *Misrepresentation and Responsibility in Medical Research*, 317 NEW ENG. J. MED. 1383, 1389 (1987); see also Warren Schmaus, *Fraud and the Norms of Science*, SCI., TECH., & HUM. VALUES, Fall 1983, at 12, 17. But see Harriet Zuckerman, *Norms and Deviant Behavior in Science*, SCI., TECH., & HUM. VALUES, Winter 1984, at 7, 11 (describing the difficulty of differentiating error from fraud in science research).

60. BROAD & WADE, *supra* note 3, at 108. One research scientist, Dr. Howard K. Schachman, in cautioning against the inclusion of inadequate record keeping as grounds for misconduct, stated that "some of the best and most imaginative scientists I know keep lousy records. We need both brilliance and freedom. We don't need legislation." Charles Marwick, *Congress Puts Pressure on Scientists to Deal with Difficult Questions of Research Integrity*, 262 JAMA 734, 734 (1989).

The precise meanings of "fabrication," "falsification," and "plagiarism" are not provided in either set of guidelines.⁶¹ Definitions of these terms have been suggested by the NAS Panel, a government-sponsored panel consisting in part of scientists, policymakers, administrators, and lawyers convened to address science misconduct.⁶² The NAS Panel defines "[f]abrication [as] making up data or results,⁶³ falsification [as] changing data or results,⁶⁴ and plagiarism [as] using the ideas or words of another person without giving appropriate credit."⁶⁵

Both the PHS and the NSF also include "serious deviation from accepted practices" as a category of actionable misconduct. Neither set of guidelines elaborates on what might constitute serious deviation. However, the DHHS has released a report which enumerates practices that could be actionable under this category:

Misuse by a journal referee of privileged information contained in a manuscript, [f]abrication of entries or misrepresentation of the publication status of manuscripts referenced in a research bibliography, [f]ailure to perform research supported by a PHS grant while stating in progress reports that active progress has been made, [i]mproper reporting of the status of subjects in clinical research . . . , [p]reparation and publication of a book chapter listing co-authors who were unaware of being named as co-authors, selective report-

61. Andersen argues that the scientific community is ultimately responsible for establishing the standards for what constitutes scientific misconduct. Andersen, *supra* note 52, at 126-27.

62. See NAS PANEL, *supra* note 2, at 27.

63. An archetypal example of wholesale fabrication is that of Sir Cyril Burt. Burt was a psychologist who contended that 75% of intelligence is inherited, a theory purportedly based on years of research with separated identical twins. According to his biographer, L.S. Hearnshaw, Burt's theories "were widely quoted, widely accepted as valid, and were among the strongest piece of evidence for the preponderantly genetic determination of intelligence." BROAD & WADE, *supra* note 3, at 205. The shortcoming of Burt's theory was that "both data and co-workers [were summoned] from the vasty deep of his tormented imagination, and clothed . . . so well in the semblance of scientific argument that the illusion fooled all his fellow scientists for as much as thirty years." *Id.* at 204.

64. Gregor Mendel, often referred to as the father of modern genetics, has often been posthumously accused of falsifying his data. Statistical analysis of the data compiled by Mendel on inheritance of genetic characteristics in peas is generally agreed to be too good to be true, leading to assertions that Mendel's data was either falsified or selectively reported. R.A. Fisher, a statistician who analyzed Mendel's data, reasoned that Mendel's results would occur "only once in 30,000 repetitions." R.A. Fisher, *Has Mendel's Work Been Re-discovered?*, 1 ANNALS OF SCI. 115, 123 (1936), cited in SAPP, *supra* note 3, at 110.

65. Probably the most extraordinary example of plagiarism in recent years is that of Elias Alsabti. Alsabti copied papers published in obscure journals word for word (except for the authors' names) and then resubmitted the paper, in his name, to a second obscure journal. Upon acceptance, Alsabti added the publication to his resume. In the course of plagiarizing as many as sixty papers, Alsabti "lied his way into U.S. universities [Alsabti was originally from Iraq], . . . bestowed a Ph.D. upon himself, [and 'forged a medical degree']." BROAD & WADE, *supra* note 3, at 38-52.

ing of primary data,⁶⁶ [u]nauthorized use of data from another investigator's laboratory, [e]ngaging in inappropriate authorship practices on a publication and failure to acknowledge that data used in a grant application were developed by another scientist, and [i]nappropriate data analysis and use of faulty statistical methodology.⁶⁷

The proscription of practices that fall outside of outright fabrication, plagiarism, or falsification is controversial because the categories are poorly defined. The NAS Panel unanimously rejected the notion that "serious deviations from acceptable research practices" could be actionable misconduct, stating that "the vagueness of this category has led to confusion about which actions constitute misconduct in science."⁶⁸ In particular, the NAS Panel "wishe[d] to discourage the possibility that a misconduct complaint could be lodged against scientists based solely on their use of novel or unorthodox research methods."⁶⁹ The NAS Panel was concerned that "[t]he use of ambiguous terms in regulatory definitions invite[d] exactly such an overexpansive interpretation."⁷⁰ Such vague definitions must be re-

66. Some commentators argue that selective reporting of primary data is a particularly inappropriate basis for a finding of misconduct. See, e.g., SAPP, *supra* note 3, at 15 (maintaining that this reflects the simplistic view that "when a scientist makes an observation or carries out an experiment, his or her mind *should be* an empty vessel ready to receive whatever information the reality of nature reveals to it" (emphasis in original)). Sapp argues instead that "[i]t is one's expectations and theoretical understanding of the laws of nature that tell the observer what is a good experiment and what is a failed experiment, what are good data and what are bad or insignificant data that can be ignored and kept unpublished." *Id.*

67. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FIRST ANNUAL REPORT: SCIENTIFIC MISCONDUCT INVESTIGATIONS REVIEWED BY OFFICE OF SCIENTIFIC INTEGRITY REVIEW MARCH 1989—DECEMBER 1990 (1991), cited in NAS PANEL, *supra* note 2, at 86.

68. NAS PANEL, *supra* note 2, at 27.

69. *Id.*

70. *Id.* While rejecting the "serious deviations from acceptable practice" category, some Panel members did believe that "misuse of the peer-review system to penalize competitors, deceptive selection of data or statistical analysis, or encouragement of trainees to practice misconduct in science" should be included in its definition of misconduct. *Id.* The Panel also enumerated "questionable research practices," which, while in violation of "traditional values of the research enterprise" and possibly "detrimental to the research process," did "not meet the panel's criteria for inclusion in the definition of misconduct in science." These practices include such activities as:

Failing to retain significant research data for a reasonable period; [m]aintaining inadequate research records, especially for results that are published or are relied on by others; [c]onferring or requesting authorship on the basis of a specialized service or contribution that is not significantly related to the research reported in the paper; [r]efusing to give peers reasonable access to unique research materials or data that support published papers; [u]sing inappropriate statistical or other methods of measurement to enhance the significance of research findings; [i]nadequately supervising research subordinates or exploiting them; and [m]isrepresenting speculations as fact or releasing preliminary research results . . .

placed with clear, detailed definitions which describe actionable conduct with specificity.⁷¹

B. The Prevalence of Misconduct in Science

Before 1989, the NIH received an average of fifteen to twenty reports of alleged science misconduct per year.⁷² The NSF investigated twelve charges of misconduct total from 1980 to 1987.⁷³ In March 1989, the PHS created the OSI⁷⁴ to deal with cases of alleged misconduct. From the time of OSI's creation to June 1991, it received 174 reports of alleged misconduct.⁷⁵ Nineteen of these cases ended with convictions, and eighty-six cases were dismissed.⁷⁶ These numbers represent a tiny fraction of the total research conducted in the same period.⁷⁷

Several commentators argue, however, that misconduct in science is grossly underreported.⁷⁸ Support for this position can be found in several independent surveys that address science misconduct. For ex-

without providing sufficient data to allow peers to judge the validity of the results or to reproduce the experiments.

Id. at 28.

71. See *infra* text accompanying notes 295-298 for a discussion of ways the definitions can be improved.

72. *Fraud in NIH Grant Programs: Hearings Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 100th Cong., 2nd Sess. 172 (1988) (statement of R.E. Windom, Assistant Secretary for Health, Department of Health and Human Services), *quoted in* Marcia Angell & Arnold S. Relman, *Fraud in Biomedical Research: A Time for Congressional Restraint*, 318 NEW ENG. J. MED. 1462, 1462 (1988). This number refers only to research funded by extramural programs of NIH.

73. Patricia K. Woolf, *Deception in Scientific Research*, 29 JURIMETRICS J. 67, 74 (1988) [hereinafter Woolf, *Deception in Scientific Research*].

74. See *infra* note 110 and accompanying text.

75. Wheeler, *supra* note 4, at A1 (statement of Dr. Lyle W. Bivens, former director of the Office of Scientific Integrity Review (the office which reviews the investigations of Office of Science Integrity), and present director of Division of Policy and Education, Office of Research Integrity).

76. *Id.*

77. NIH, for example, was supporting approximately 50,000 scientists when these reports were received. *Id.*

78. Several reasons have been given for the underreporting. These include hesitancy on the part of junior scientists to report misconduct of senior scientists. For example, 50% of the confirmed cases of misconduct between 1980 to 1987 involved individuals having a rank of full or associate professor, or senior scientist or laboratory chief. NAS PANEL, *supra* note 2, at 91 tbl. 4.3. Furthermore, it is difficult to identify misconduct. The editor of *Science*, Daniel E. Koshland, stated that "[d]etecting fraud from a reading of the scientific article is very difficult. In most cases, a clever deceiver can falsify data in such a way that a reviewer can be fooled." Marwick, *supra* note 60, at 735. The scientific community has been unable to reach consensus as to what constitutes misconduct. See *supra* Part I.A. In addition, the confirmed cases do not reflect the incidents of alleged misconduct that were dealt with entirely by the research institutions in which they occurred. One commentator suggests that "plagiarism is almost certainly underrepresented . . . as it appears to be han-

ample, a series of routine audits conducted by the Food and Drug Administration from June 1977 to September 1983 of investigators testing new drugs found serious deficiencies in 11.5 percent of the cases.⁷⁹ The British journal *New Scientist* conducted a survey in which ninety-two percent of the readers returning questionnaires indicated that they knew of or suspected cases of "intentional bias."⁸⁰ A third study, which surveyed the exposure of graduate school deans to misconduct, indicated that forty percent of the responding deans had received reports of possible faculty misconduct in science during the previous five years.⁸¹ Twenty percent of these deans indicated that the reports were verified.⁸²

These surveys indicate that misconduct may occur more frequently than the number of reported cases each year suggests; however, they are fraught with ambiguities.⁸³ In the absence of a definitive survey on the subject, the discrepancy between the number of confirmed incidents of misconduct⁸⁴ and the preceding survey estimates makes it clear that no one really knows the extent of misconduct in science.⁸⁵

dled locally and without publicity whenever possible." Woolf, *Deception in Scientific Research*, *supra* note 73, at 83.

79. Martin F. Shapiro & Robert P. Charrow, *Scientific Misconduct in Investigational Drug Trials*, 312 NEW ENG. J. MED. 731, 733, 736 (1985). The authors warn, however, that "these data must be interpreted with caution. Some trials that were judged to be seriously deficient may have been instances of [for example] extensive technical violations of FDA regulations, rather than instances of scientific misconduct." *Id.*

80. Ian St. James-Roberts, *Cheating in Science*, 72 NEW SCIENTIST 466, 466-69 (1976) (based on 204 responses from 70,000 solicitations).

81. J.P. Swazey et al., *University Policies and Ethical Issues in Research and Graduate Education: Highlights of the CGS Dean's Survey*, 22 CGS COMMUNICATOR 1, 1-3, 7-8 (1989), *cited in* NAS PANEL, *supra* note 2, at 92.

82. Swazey et al., *supra* note 81, at 1-3, 7-8, *cited in* NAS PANEL, *supra* note 2, at 93.

83. See NAS PANEL, *supra* note 2, at 97 n.15 (stating that of the respondents to the St. James-Roberts survey claiming experiences with bias, in 52% of the cases the source of knowledge was direct and in 40% of the cases the source was indirect (*i.e.*, "information from colleagues, scientific grapevine, media")). *But see* BROAD & WADE, *supra* note 3, at 85 (arguing that because the St. James-Roberts survey data was derived from only 204 responses out of a total 70,000 solicited, its conclusion is of dubious value).

84. See *supra* text accompanying notes 72-75.

85. See Rosemary Chalk, *Workshop Summary*, in AAAS-ABA CONFERENCE, *supra* note 3, at 1, 3-4 (discussing the difficulty in determining the level of misconduct in science when "[t]here is no uniform definition for scientific misconduct and various institutions use different criteria in investigating allegations of fraud, plagiarism, or other deviations from generally accepted research practice"); see also OFFICE OF INSPECTOR GEN., NATIONAL SCIENCE FOUND., No. OIG 90-3214, SURVEY DATA ON THE EXTENT OF MISCONDUCT IN SCIENCE AND ENGINEERING 9 (1990) (reporting that "the full extent of misconduct is not yet known").

C. Harm from Scientific Misconduct

The potential for harm to the scientific community from misconduct in science research is no longer seriously disputed,⁸⁶ particularly given the recent spate of well-publicized cases.⁸⁷ In addition to losing credibility in the public eye, scientists who rely on fraudulent data waste scarce research funds and years of effort (and possibly career advancement) by pursuing fruitless research. From the government's perspective, the waste of tax dollars is "probably not the most important concern"⁸⁸ (although taxpayers may take issue with this position). Instead, the main consideration is protecting the public welfare.⁸⁹ Scientific research in the field is the first step in developing and marketing pharmaceutical products and medical devices. Products developed using fraudulent data—for example, using fraudulent testing practices for new drugs⁹⁰—place the public at serious and unacceptable risk.

Another concern of both the government and the individual scientist is the effect of misconduct on intellectual property rights. Patent claims based on fraudulent research sap the limited resources of the Patent and Trademark Office, and can deter other scientists from filing legitimate claims.⁹¹

86. See NAS PANEL, *supra* note 2, at 95 (concluding that "[r]egardless of the incidence . . . even infrequent cases of misconduct in science are serious matters"); accord Albert H. Teich, *Foreword*, in AAAS-ABA CONFERENCE, *supra* note 3, at v (stating that allegations of science misconduct, "even if relatively limited in scope . . . [undermine] the structure of scientific knowledge and . . . [endanger] the base on which public support of research rests").

87. See *supra* notes 8-42 and accompanying text.

88. See, e.g., Andersen, *supra* note 52, at 122 (stating that "reasons for these attempts to control, prevent, and remedy scientific misconduct extend far beyond the government's concern with fraud, waste, and abuse . . . [M]any view the government as having a prominent role in controlling the adverse side effects of technological growth on public health and safety.").

89. *Id.*

90. See Shapiro & Charrow, *supra* note 79.

91. For example, a scientist who has created a patentable process or product may be deterred from filing a claim for a patent if she learns a patent has already been issued for the same product or process. If the preempting patent was based on fraudulent data, however, the "second" inventor would suffer a grave injustice. Not only might the "second" inventor abandon ultimately patentable research, but the doctrine of "prior art" may make the product ultimately unpatentable.

By law, the United States Patent and Trademark Office can only issue patents for inventions that have not been in public use (or on sale) for more than twelve months before the filing of the patent application. 35 U.S.C. § 102(b) (Supp. I 1989). Because of this, inventors do not publicize their inventions with enough detail to allow "one skilled in the art" to replicate the invention more than one year before filing for a patent. If they did, the invention could become part of the public domain, and no patent would issue. *Id.*

This rule of patent law can backfire, however, when a patent is issued for an invention that was created with knowledge gained through scientific misconduct. A second inventor who legitimately develops an improperly patented product may believe that she lacks a

Notwithstanding these harms, many commentators have urged that efforts to remedy the problem of scientific misconduct be undertaken with caution, lest research be chilled.⁹² A second source of hesitancy may be that of the usual impetus to maintain the status quo.

D. Causes of Scientific Misconduct

When Congress had its first hearing on fraud in scientific research, its first witness was Phillip Handler, former president of the National Academy of Sciences. In discussing the causes of fraud in science, Handler told former Congressman Albert Gore, Jr.'s subcommittee of the House Committee on Science and Technology, "[O]ne can only judge the rare . . . acts that have come to light as psychopathic behavior originating in minds that have made very bad judgments—ethics aside—minds which in at least this one regard may be considered . . . deranged."⁹³ Handler's statement reflected the prevailing sentiment in the scientific community, before the highly-publicized disclosures of the last decade, that "instances of falsification are rare transgressions, alien to common professional experience and attributable to an individual scientist's aberrant behavior."⁹⁴ This "bad apple" theory maintains that misconduct results from inherent personal deficiencies.

An alternative to the bad apple theory of misconduct's cause is the "environmental influences" theory.⁹⁵ The environmental influ-

legitimate claim to a patent, and therefore may publish her results without filing a patent claim. If enough time passes (*i.e.*, more than one year) before the fraudulent patent claim is exposed and the legitimate inventor files her claim (*i.e.*, if the legitimate inventor fails to file within a year of publishing on her invention), the "second" inventor's legitimate patent claims would be foreclosed forever. The effect of this loss would go beyond the researcher denied the patent. Private industry may be less likely to develop products that lack patents, potentially depriving the public of useful pharmaceutical products.

92. See, *e.g.*, Chalk, *supra* note 85, at 26 ("Unnecessary and wasteful investigations of insignificant incidents of misconduct or malicious complaints may damage collegial trust and distort the traditional values of the academic environment."); Patricia K. Woolf, *Science Needs Vigilance not Vigilantes*, 260 JAMA 1939, 1940 (1988) (cautioning that "the scientist who will take no chances on being wrong has little likelihood of making a major discovery . . . If scientists think they will be pilloried for making errors, scientific progress will cease."); see also Andersen, *supra* note 52, at 129 ("While fabrication of data is scientific sin, theoretical flights of fantasy and creative hypotheses are the mark of Nobel Prize-winning work. Establishing standards capable of adequately distinguishing instances of self-deception from misconduct, and theorizing from deception, is an extremely difficult task."). In response to concerns that research will be chilled by allegations made out of malice, it should be noted that neither the PHS nor the NSF advocate protections against whistleblowers who act in bad faith.

93. *Hearings*, *supra* note 5, at 12.

94. Patricia Woolf, *Fraud in Science: How Much, How Serious?*, HASTINGS CENTER REP., Oct. 1981, at 9, 10 [hereinafter Woolf, *Fraud in Science*].

95. NAS PANEL, *supra* note 2, at 30; see also Philip W. Majerus, *Fraud in Medical Research: Presidential Address Delivered Before the 74th Annual Meeting of the American*

ences theory argues that extrinsic forces lead to misconduct.⁹⁶ The NAS Panel has summarized factors in the research environment that may contribute to misconduct. These include:

(1) funding and career pressures . . . ; (2) inadequate institutional oversight; (3) inappropriate forms of collaborative arrangements between academic scientists and commercial firms; (4) inadequate training in the methods and traditions of science; (5) the increasing scale and complexity of the research environment, leading to the erosion of peer review, mentorship, and educational processes in science; and (6) the possibility that misconduct in science is an expression of a broader social pattern of deviation from traditional norms.⁹⁷

These views shape theories on the most effective way to deal with misconduct. Under the bad apple view, the most effective way to deter misconduct might be to attempt to detect aberrant behaviors. Under the environmental influences view, the whole community is culpable and remedies must consider the entire structure.⁹⁸

II. Current Approaches to the Problem of Scientific Misconduct

Robert Merton was the first individual to articulate norms for science activity. In 1942, Merton identified the norms as (1) universal-

Society for Clinical Investigation, 70 J. CLIN. INVEST. 213, 213-14 (1982) (claiming that "there is a qualitative difference between today's investigators and those of the past. The stake in 'results' was less. The pressure to produce is inevitable . . . [and] may contribute to a loss of perspective. [Other factors contributing to misconduct are that of] striving for stardom . . . [or either an] unscrupulous mentor who pressures fellows and students for 'results' to obtain or maintain stardom . . . [or an] 'absent' mentor, [providing inadequate] supervision.""). As support for the environmental model, one authority, Barbara Mishkin, observed that "65% of the cases of misconduct involved persons with M.D. degrees, while 23% involved persons with Ph.D. degrees . . . [suggesting that this is] a reflection of the differences in the training and supervision of research practices of Ph.D. candidates compared with M.D. candidates." Marwick, *supra* note 60, at 734-35.

96. NAS PANEL, *supra* note 2, at 30-31.

97. *Id.*; see also SAPP, *supra* note 3, at 10 (suggesting that the nature of big science with the inevitable "quest for big money to finance huge laboratory factories" is a contributing factor to incidences of scientific misconduct). In response to the pressures to publish placed on scientists, Harvard Medical School has now changed its hiring policy by considering only five articles when evaluating an applicant for assistant professor, seven for associate professor, and 10 for full professor (instead of having an unlimited number of publications which could be considered). Harvard University Faculty of Medicine, *Harvard Guidelines for Investigators in Scientific Research*, 37 CLIN. RES. 192, 193 (1989).

98. Support for the latter view was voiced by Robert Ebert, former dean of the Harvard Medical School, who "called upon the profession not to rely on 'human frailty and nothing more' as the sole explanation of fraud in science; he urged the scientific community to pay heed to the role of institutional factors and the characteristics of the research environment." Robert Ebert, *Letter to the Editor*, N.Y. TIMES, June 9, 1980, quoted in Woolf, *Fraud in Science*, *supra* note 94, at 10.

ism—science should be judged on its inherent content, not on the personal reputations of its authors; (2) communism—scientific findings should be shared; (3) organized skepticism—scientific results should be subjected to “detached scrutiny of beliefs in terms of empirical and logical criteria”; and (4) disinterestedness—the scientist’s priority should be to ascertain the truth, not to advance herself personally.⁹⁹ These norms operated so effectively, Merton believed, that the result was the “virtual absence of fraud in the annals of science.”¹⁰⁰

Phillip Handler echoed this view in his appearance before the Gore subcommittee, stating that “[s]cientific fraud happens rarely, and when it does . . . ‘it occurs in a system that operates in an effective, democratic and self-correcting mode’ that makes detection inevitable.”¹⁰¹ But even before the recent publicity surrounding scientific fraud, this sentiment was overly charitable. For hundreds of years prominent scientists have been suspected of scientific fraud—Newton, Mendel, Dalton, and Milliken, among others.¹⁰²

A. The Public Health Service

In 1985, the PHS received a congressional mandate to promulgate regulations establishing policies and procedures for handling alleged misconduct.¹⁰³ Congress also required institutions receiving PHS research funds to establish an “administrative process to review reports of scientific fraud . . . [and to] report to the Secretary [of the DHHS] any investigation of alleged scientific fraud which appears substantial.”¹⁰⁴ In addition, the institutions were directed to assure the DHHS that such procedures were in place.¹⁰⁵

99. R.K. MERTON, *THE NORMATIVE STRUCTURE OF SCIENCE* (1942), reprinted in *THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATION* 267, 267-78 (N.W. Storer ed., 1973). For a more contemporary perspective on the norms of science, see Andre Cournand, *The Code of the Scientist and its Relationship to Ethics*, 198 *SCIENCE* 699 (1977) (proposing that the norms of science are principally honesty, objectivity, tolerance, doubt of certitude, unselfish engagement, and the ethic of development).

100. MERTON, *supra* note 99, at 276.

101. *Hearings*, *supra* note 5, at 11 (statement of Dr. Phillip Handler, president, National Academy of Sciences), quoted in BROAD & WADE, *supra* note 3, at 11-12.

102. BROAD & WADE, *supra* note 3, at 23.

103. See Health Research Extension Act of 1985, Pub. L. No. 99-158, § 493(a), 99 Stat. 820, 874 (1985).

104. *Id.* The administrative processes established by the awardee institutions are not, however, subject to NIH approval. The PHS regulation states that “legislation does not require, and PHS does not intend to require, agency approval of institutional procedures, nor is it intended that the regulations will spell out in detail the administrative requirements for institutional procedures.” National Institutes of Health, *Misconduct in Science Assurance*, 17 NIH GUIDE FOR GRANTS AND CONTRACTS 1, 2 (1988).

105. 42 C.F.R. § 50.103 (1992).

The PHS assigns primary responsibility for conducting inquiries and investigations to the institutions.¹⁰⁶ Each awardee institution also has the responsibility for establishing its own policies and procedures for use in these proceedings.¹⁰⁷ On August 8, 1989, the PHS published its final rule on "Responsibilities of Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science"¹⁰⁸; this publication was followed on June 13, 1991 by a notice of "Policies and Procedures for Dealing with Possible Scientific Misconduct in Extramural Research."¹⁰⁹

To aid the PHS in enforcing these policies, the OSI and OSIR were created by the Office of the Director of the NIH, which is a branch of the PHS.¹¹⁰ In 1992, the OSI and OSIR were superseded by the ORI, which is also part of the NIH.¹¹¹ The ORI has only issued interim procedures; these interim procedures will become final after they are published in the Federal Register and subsequently revised before final adoption, following public comment.¹¹² The regulations issued by OSI and OSIR before their dissolution are the only procedures that have been finalized by the PHS. These OSI-OSIR rules are therefore discussed first, followed by the interim procedures promulgated by ORI.

106. 42 C.F.R. § 50.104(a)(6) (1992).

107. 42 C.F.R. § 50.101 (1992).

108. Responsibilities of Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science, 54 Fed. Reg. 32,446 (1989) (codified at 42 C.F.R. § 50.101-105 (1992)).

109. Policies and Procedures for Dealing with Possible Scientific Misconduct in Extramural Research, Notice of Policies and Procedures, 56 Fed. Reg. 27,384, 27,389 (Dep't Comm. 1991) [hereinafter Policies and Procedures]. Extramural research refers to research that is funded by the PHS, but not conducted at a PHS institute.

110. 42 C.F.R. § 50.102 (1992). Although OSI was established within NIH, it had PHS-wide authority. The OSI had four major duties: "[(1)] implement[ing] . . . all PHS policies and procedures related to matters of scientific misconduct; [(2)] monitor[ing] the individual investigations into alleged or suspected scientific misconduct conducted by institutions that receive PHS funds . . . ; [(3)] . . . conduct[ing] investigations as necessary," *id.*; and "[(4)] participat[ing] in and direct[ing] preventive and educational measures to encourage the responsible conduct of research." Jules V. Hallum & Suzanne W. Hadley, *OSI: Why, What, and How*, 56 ASM NEWS 647, 649 (1990).

The OSIR was created at the same time as the OSI, and is responsible for establishing overall PHS policies and procedures for dealing with misconduct in science, overseeing the activities of PHS research agencies to ensure that these policies and procedures are implemented, and reviewing all final reports of investigations to assure that any findings and recommendations are sufficiently documented. The OSIR also makes final recommendations to the Assistant Secretary of Health whether sanctions should be imposed, and if so, what they should be in any case in which scientific misconduct has been established. 42 C.F.R. § 50.102 (1992).

111. 42 C.F.R. § 50.102; Statement of Organization, Functions and Delegations of Authority, Action Notice, 57 Fed. Reg. 24,262 (1992) [hereinafter Statement of Organization].

112. Opportunity for a Hearing on Office of Research Integrity Scientific Misconduct Findings, 57 Fed. Reg. 53,125 (1992) [hereinafter ORI Hearings].

The OSI and OSIR have described their approach as the "scientific dialogue" model.¹¹³ The scientific dialogue model does not provide opportunity to confront and cross-examine witnesses, but instead relies on the scientist to provide a written presentation of her case; this presentation is followed by individual interviews of pertinent witnesses.¹¹⁴

The OSI and OSIR divided the misconduct proceeding into a two-part process—an inquiry followed by an investigation.¹¹⁵ The procedures provided for notice to the accused about any impending inquiries or investigations, and appraisal of the allegations to be investigated.¹¹⁶ The procedures also allowed the accused representation by counsel, and opportunity to present witnesses to be interviewed.¹¹⁷ Individuals accused of misconduct were provided transcripts of all interviews and were given any research data under review, as well as an opportunity to comment on and rebut charges in writing.¹¹⁸ Accused individuals were also permitted personal interviews,¹¹⁹ but were not allowed to confront and cross-examine witnesses.¹²⁰ Instead, they were given "an opportunity to comment and rebut in writing on the findings or proposed sanctions, if any," at the conclusion of the proceedings.¹²¹ The findings, along with any changes resulting from the accused's comments, were then forwarded to the Assistant Secretary of Health, who adjudicated sanctions.¹²² Findings that proposed debarment had to be approved by the Deputy Assistant Secretary for Management and Acquisition.¹²³ If debarment was proposed, the scientist under review could request de novo review at an administrative hearing.¹²⁴ Findings in misconduct cases investigated by academic institutions that involved PHS funds were reviewed by OSI for timeliness, objectivity, thoroughness, and competence.¹²⁵ The OSI then

113. Hallum & Hadley, *supra* note 110, at 650.

114. *Id.* For a criticism of this approach, see David P. Hamilton, *Can OSI Withstand a Scientific Backlash?*, 253 SCIENCE 1084 (1991).

115. Inquiry, as defined by the PHS, means "information-gathering and initial fact-finding to determine whether an allegation or apparent instance of misconduct warrants an investigation." 42 C.F.R. § 50.102. Investigation, as defined by the PHS, means the "formal examination and evaluation of all relevant facts to determine if misconduct has occurred." *Id.*

116. 42 C.F.R. § 50.103(d)(1), (3).

117. Policies and Procedures at 27,387.

118. *Id.* at 27,388.

119. *Id.*

120. *Id.*

121. *Id.*

122. *Id.*

123. *Id.*

124. *Id.*

125. 42 C.F.R. § 50.104(a)(6).

made a determination whether to accept these findings, or to conduct its own investigation.¹²⁶

These OSI procedures were superseded on November 6, 1992, by an interim procedure established by ORI.¹²⁷ Under the ORI procedures, each time the ORI makes a finding of scientific misconduct, the respondent is entitled to an administrative hearing.¹²⁸ Recipients of PHS funds found guilty of misconduct in a university investigation are also offered a hearing.¹²⁹ The hearing allows for representation by counsel, examination of "any evidence and witnesses presented by ORI," and the presentation of witnesses and evidence "in rebuttal to the findings and proposed administrative actions."¹³⁰

The administrative hearing is conducted by an entity outside of the ORI—the DHHS Departmental Appeals Board (DAB).¹³¹ The DAB appoints a Chairman to a Research Integrity Adjudications Panel, which conducts the hearings.¹³² The DAB also may appoint up to two additional individuals with relevant technical or scientific expertise to the panel.¹³³ For cases in which debarment is recommended, the respondent is offered a consolidated hearing, covering the "ORI findings of misconduct and administrative actions and the proposed debarment."¹³⁴ As of January 1992, the ORI had received requests for seven hearings.¹³⁵

The ORI also maintains the PHS ALERT system. This record-keeping method maintains files not only on individuals who have been the subject of investigations and on whom sanctions have been imposed, but also on individuals who are under investigation or about whom decisions have been made not to conduct an investigation. Information is disseminated to PHS officials "on a need-to-know basis."¹³⁶ As the NAS Panel reports:

OSI (now replaced by ORI) searches the PHS ALERT system on a regular basis to compare the records it contains with the list of PHS grant recipients. The name of an investigator on file in the . . . system may be submitted to the finding directors of an institute, who

126. *Id.*

127. Statement of Organization at 24,262.

128. ORI Hearings at 53,125.

129. *Id.*

130. *Id.*

131. *Id.*

132. *Id.*

133. *Id.* For a discussion of conflicts which have arisen between the two entities, see *supra* notes 39-41 and accompanying text.

134. *Id.*

135. Telephone Interview with Dr. Lyle W. Bivens, *supra* note 39.

136. Policies and Procedures at 27,393.

may use the information in making decisions about, for example, advisory committee appointments and grant extensions.¹³⁷

The PHS guidelines propose a range of sanctions when a finding of science misconduct is made. These are arranged in groups of increasing severity. Group I sanctions range from "a letter of reprimand for improper action to the individual and/or institution" to requiring "supervision or oversight of scientific activities of the individual found guilty of misconduct."¹³⁸ Group II sanctions range from restriction "for a specified period of time, [of] specific activities or expenditures under an active award" to restriction of "participation . . . on peer review committees, advisory groups or in other related PHS activities for a specified period of time."¹³⁹ Group III sanctions range from immediate suspension or termination of active awards to debarment or suspension for a specified period of time, "declaring him or her ineligible . . . for any participation in Federal grants and cooperative agreements and . . . contracts."¹⁴⁰

B. The National Science Foundation

Like the PHS, the NSF relies on awardee institutions to devise their own procedures for handling cases of misconduct.¹⁴¹ The NSF requires that institutions conduct inquiries within ninety days, and investigations, if warranted, within 180 days.¹⁴² Outside of these constraints, however, the "institutions have broad discretion in how to handle their misconduct cases."¹⁴³ Institutions may handle allegations of research misconduct "in a manner they find to be most appropriate."¹⁴⁴

Awardee institutions have the option of requesting the NSF to conduct the investigation.¹⁴⁵ The NSF coordinates investigations through the Office of Inspector General (OIG).¹⁴⁶ The OIG evalu-

137. NAS PANEL, *supra* note 2, at 110. The NAS Panel concluded that the "use of the PHS ALERT system in disclosing the identities of individuals who are under investigation for possible misconduct in science is a serious flaw in the fairness of current governmental policies and procedures." *Id.* at 111.

138. Policies and Procedures at 27,393 (citations omitted).

139. *Id.* (citations omitted).

140. *Id.* (citations omitted). The PHS states that these sanctions "are provided for guidance." *Id.* In addition to these sanctions, "PHS may also seek to recover funds if they were expended for research that was fabricated, falsified or otherwise invalid because of misconduct in science and recovery from the institution is otherwise deemed appropriate." *Id.*

141. 45 C.F.R. § 689.3(a) (1991).

142. 45 C.F.R. § 689.3(c).

143. Misconduct in Science and Engineering at 22,286.

144. *Id.* at 22,286.

145. 45 C.F.R. § 689.3(b).

146. 45 C.F.R. § 689.4(a).

ates reports of findings made by awardee institutions for "accuracy and completeness and [determines] whether the investigating entity followed usual procedures."¹⁴⁷ The OIG then either adopts the findings of the research institution or initiates a new investigation.¹⁴⁸

NSF misconduct proceedings have been described as "legal-adversarial"¹⁴⁹ because the NSF allows the accused to appeal the decision.¹⁵⁰ NSF investigations normally provide notice and an opportunity to comment and rebut before final action is taken.¹⁵¹ However, no provision is made for confrontation and cross-examination of witnesses by the accused. The NSF also provides the opportunity for appeal, which the OSI regulations do not (unless the recommended sanction is debarment¹⁵²). For cases in which debarment or suspension is recommended, further procedures described in debarment and suspension regulations are applicable.¹⁵³ These regulations state that these procedures may also include opportunity to be heard¹⁵⁴ and full adjudicatory hearings,¹⁵⁵ or "other formal proceedings."¹⁵⁶

The NSF guidelines incorporate safeguards to minimize damage to the respondent's reputation during this process:

To avoid influencing reviews, reviewers or panelists will *not* be informed of allegations or of ongoing inquiries or investigations. However, if allegations, inquiries, or investigations have been rumored or publicized, the responsible Assistant Director may, in consultation with OIG, either defer review or inform reviewers of the status of the matter.¹⁵⁷

Although this approach is designed to mitigate the harm to the accused that may result from rumor and innuendo, it may have the opposite effect. Rumors of allegations plant seeds in reviewers' minds—that is, the reviewers know that allegations have been made, whether or not they have merit. There is always the danger that reviewers on grant-funding panels will decide the fact that the accused (or even the not-yet-accused, in the case of an individual who is merely the subject of an inquiry) is being investigated for misconduct is a reason to look askance at the accused's grant proposal. For this reason a subsequent

147. 45 C.F.R. § 689.8(a).

148. *Id.*

149. NAS PANEL, *supra* note 2, at 113.

150. 45 C.F.R. § 689.9(a).

151. 45 C.F.R. § 689.1(d).

152. 45 C.F.R. § 76.313 (1989).

153. Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace, 45 C.F.R. pt. 620 (1991).

154. 45 C.F.R. § 689.5(d)(6).

155. 45 C.F.R. § 689.5(d)(7).

156. *Id.*

157. 45 C.F.R. § 689.6(b).

finding of "no misconduct" may come too late to restore a grant denied funding. The sanctions provided in the NSF guidelines parallel those used by the PHS.¹⁵⁸

Thus, notwithstanding the views of Dr. Handler,¹⁵⁹ funding agencies are seriously addressing scientific misconduct. The present challenge is to shape those responses to maximize due process¹⁶⁰ while minimizing the incidence of science misconduct in the laboratory.¹⁶¹ This goal may remain elusive in the funding agencies if the agencies are not the appropriate venue for staging the misconduct proceedings.¹⁶²

C. Universities and Other Research Institutions

The range of institutional policies for dealing with research misconduct was the subject of a survey conducted by Penelope Greene and others from late 1982 to early 1984.¹⁶³ Questionnaires were sent to 747 academic institutions and hospitals. Out of the 493 responding institutions, 116 had written policies for dealing with allegations of misconduct; 124 institutions had "[no policies] at all and no plans to formulate any"¹⁶⁴; and the other responding institutions were in the process of formulating policies at the time of the survey. Of the 116 institutions with written policies, sixty-nine percent had procedures

158. 45 C.F.R. § 689.2.

159. See *supra* text accompanying notes 93, 110, 111.

160. This issue is explored in further detail in Part III, *infra*. The protections proffered by the DAB include most elements of due process. However, the defects in misconduct definitions undermine notice. Furthermore, this is still an interim procedure.

161. The present DAB standard for intent may, in fact, shift the focus away from misconduct in the lab, solely focusing on fraudulent research conclusions. The DAB standard requires a showing that a "deliberate intent to deceive" had a significant impact on the conclusion of the paper. Hilts, *Misconduct Charges Dropped*, *supra* note 40. As stated by one investigator, that standard "is even more rigorous than 'beyond a reasonable doubt'. . . ." *Id.* Perhaps more significantly, fraud which supports an otherwise valid conclusion is not actionable. Furthermore, even deliberate fraud in the lab would be acceptable so long as no publications result. The latter consequence would seem to suggest that scientists can lie about their results (on grant applications, for example) without fear of reprisal. One can only hope that the current DAB standard for determining intent is temporary.

162. This issue is explored in depth in Part IV.A, *infra*.

163. Penelope J. Greene et al., *Policies for Responding to Allegations of Fraud in Research*, 23 MINERVA 203 (1985). For additional studies on research institution and professional society policies for handling misconduct, see AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE, PROFESSIONAL ETHICS ACTIVITIES IN THE SCIENTIFIC AND ENGINEERING SOCIETIES (1980); ASSOCIATION OF AMERICAN MEDICAL COLLEGES, THE MAINTENANCE OF HIGH ETHICAL STANDARDS IN THE CONDUCT OF RESEARCH (1982); ASSOCIATION OF AMERICAN UNIVERSITIES, REPORT OF THE ASSOCIATION OF AMERICAN UNIVERSITIES COMMITTEE ON THE INTEGRITY OF RESEARCH (1985); SIGMA XI, HONOR IN SCIENCE (1984).

164. Greene et al., *supra* note 163, at 204.

for investigation; forty-four percent had procedures for hearings; and thirty-five percent had procedures for an appeal.¹⁶⁵ The survey reported that there were "vast differences of opinion . . . as to whether institutional policies for responding to allegations of fraud in research are necessary, and[, if so,] how such policies should be implemented."¹⁶⁶

Eighty-two of the responding institutions permitted legal representation "in some fashion" in connection with misconduct investigations.¹⁶⁷ For example, one institution allowed counsel to assist in preparing documents and gathering evidence, but did not allow counsel to appear with or on behalf of the accused at hearings.¹⁶⁸ One institution allowed counsel at all stages, while another institutional approach was to "allow an attorney to sit with the committee as hearing officer to 'make all decisions on evidence and procedures, but not [to] vote on the substantive merits of the request.'"¹⁶⁹

The responses from the institutions indicate that not all of them are aware that due process is even a consideration in misconduct proceedings. Although one respondent stated that "[b]ecause procedures are not more detailed, we would need to proceed carefully to ensure the rights of the accused and to provide for due process,"¹⁷⁰ another institution drafted policies in such general terms that it was "unclear whether due process [was] provided for."¹⁷¹ The evidentiary standards used in the investigations were often poorly defined. One respondent stated that "[a]ny oral or documentary evidence may be received *so long as it is of the sort on which responsible people are accustomed to rely* in the conduct of serious affairs."¹⁷²

Since the congressional mandate that institutions receiving PHS funds formulate policies for handling allegations of misconduct,¹⁷³ the situation has improved somewhat; however, more improvement is needed. The NAS Panel reported that the size of the research institution is related to whether the institution formulates formal policies for dealing with misconduct. Although most research-intensive universities (*i.e.*, institutions with 100 or more PHS awards) had adopted such procedures by 1989, only twenty-two percent of all PHS-funded insti-

165. *Id.* at 205.

166. *Id.* at 214.

167. *Id.* at 211.

168. *Id.*

169. *Id.*

170. *Id.*

171. *Id.* at 212.

172. *Id.* at 211-12 (emphasis added).

173. See *supra* notes 103-105 and accompanying text.

tutions had done so.¹⁷⁴ The NAS Panel also noted that "substantial variation remains" in the procedures followed by the various research institutions.¹⁷⁵ The OSIR reached a similar conclusion in a report considering the status of investigative policies:

In 5 of the outside [*i.e.*, non-PHS] investigations, the subject was accompanied by legal counsel during meetings with the panel, with counsel acting in an advisory capacity. . . . One institution held a formal hearing before a five-member "Hearing Board." Provision was made for full disclosure of evidence prior to the hearing, testimony from witnesses, cross-examination of witnesses by the subject's attorney, and written and oral summary positions at the end of the hearing. . . . The time required for outside institutions to complete investigations varied from one to 12 months.¹⁷⁶

With regard to imposed sanctions, the NAS Panel reported that "[i]n misconduct cases reviewed by PHS and NSF, research institutions have sometimes imposed sanctions as a direct result of their investigations, in some cases prior to or in addition to governmental actions."¹⁷⁷

In sum, the responses of universities and other research institutes to science misconduct is uneven and often unsatisfactory. Due process protections are often ill-defined; furthermore, as evidenced by the NAS Panel report, even today there are research institutes which have yet to formally address the problem. Yet under the present policies of the PHS and the NSF, research institutes are the usual setting for both inquiry and investigation. Thus, by the time the funding agencies become involved, reputations are often already sullied. If due process protections were denied at the research institute level, the due process afforded at the agency may not only be too little, they may also be too late.

174. OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUM. SERVS., NO. OAI 88-07-00420, MISCONDUCT IN SCIENTIFIC RESEARCH 9 (1989). For examples of specific institutional approaches to handling science misconduct, see Baltimore, *supra* note 9 (describing procedures followed at Whitehead Institute); Chalk, *supra* note 85, at 12-17 (summarizing guidelines for Harvard Medical School, Stanford University, University of California at San Diego School of Medicine, and University of Virginia); Epstein, *supra* note 1, at 347-58 (describing the procedures followed by the University of Chicago for handling cases of alleged misconduct).

175. NAS PANEL, *supra* note 2, at 101.

176. Department of Health and Human Services, *First Annual Report: Scientific Misconduct Investigations Reviewed by Office of Scientific Integrity Review March 1989-December 1990*, at 4 (1991), quoted in NAS PANEL, *supra* note 2, at 103 (alteration in original).

177. NAS PANEL, *supra* note 2, at 103. Thus, even if the government entity provided due process protections, sanctions are sometimes imposed before those protections can be realized.

III. Due Process and Its Application to Science Misconduct

I will admit with you, sir, the absence of any sense of what due process should be when some suspicion is aroused [in cases of alleged science misconduct]. We have never adopted standardized procedures of any kind to deal with these . . . events.¹⁷⁸

In determining an individual's entitlement to due process, the United States Supreme Court employs a two-part test.¹⁷⁹ First, the Court asks whether a "threshold interest" that due process protects is implicated.¹⁸⁰ If a threshold interest is implicated, the Court must then determine what protections are due.¹⁸¹

Because a positive finding in a misconduct investigation can result in sanctions ranging from a reprimand to debarment from federal funds or loss of employment or both,¹⁸² the question arises when, if at all, these cases implicate a threshold interest, triggering application of the Due Process Clause of the Constitution.¹⁸³ Furthermore, the Supreme Court has never directly addressed the due process requirements for a science misconduct proceeding.¹⁸⁴ One can, however, ascertain these requirements by examining the Court's position on due process.

A. When Due Process Rights Are Triggered

Federal funding is so inextricably intertwined with a scientist's ability to pursue her profession that when federal grants are threatened by charges of misconduct, liberty interests are implicated. Misconduct proceedings that threaten a scientist's ability to obtain future federal funding implicate liberty interests as well.¹⁸⁵ This Subpart

178. *Hearings*, *supra* note 5, at 43 (statement of Phillip J. Handler).

179. *See* *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 541 (1985).

180. *Id.* at 541-42; *see infra* Part III.A.

181. *Id.* at 542-43; *see infra* Part III.B.

182. *See supra* text accompanying notes 138-140, 158.

183. *See* U.S. CONST. amend. V.

184. The constitutionality of an NIH investigation into scientific misconduct has been challenged on due process grounds in lower courts. In *Abbs v. Sullivan*, 963 F.2d 918 (7th Cir. 1992), the plaintiff argued that he had a liberty interest in continued funding and protection of his reputation. This argument had been rejected by the trial court. Nevertheless, the Seventh Circuit held that the NIH rules for conducting misconduct proceedings had not been promulgated in compliance with the Administrative Procedures Act and were hence invalid. The Seventh Circuit Court of Appeals held that "the procedural rule here in question is not judicially reviewable unless or until sanctions have been imposed under it." *Id.* at 928 (Cudahy, J., concurring in part and dissenting in part).

185. *See, e.g., Old Dominion Dairy Prods., Inc. v. Secretary of Defense*, 631 F.2d 953, 961-62 (D.C. Cir. 1980) (holding that a due process liberty right was violated when the government rejected bids for government contracts based on an agency determination that a bidder lacked integrity and responsibility, without notifying the bidder that its integrity was at issue); *Larry v. Lawler*, 605 F.2d 954, 963 (7th Cir. 1978) (holding that a bar from

argues that due process protections must be extended to science misconduct proceedings to safeguard these liberty interests.

(1) *A Liberty or Property Interest Must Be Implicated Before Due Process Protections Arise*

Under the Fifth and Fourteenth Amendments of the United States Constitution, due process of law must be satisfied before government may deprive persons of life, liberty, or property.¹⁸⁶ The Court explained what constitutes a liberty interest in *Meyer v. Nebraska*:¹⁸⁷

[Liberty interests] denote not merely freedom from bodily restraint but also the right of the individual to contract, to engage in any of the common occupations of life, to acquire useful knowledge, to marry, establish a home and bring up children . . . and generally to enjoy those privileges long recognized at common law as essential to the orderly pursuit of happiness by free men.¹⁸⁸

The Court extended the *Meyer* liberty and property interests in *Bell v. Burson*,¹⁸⁹ forgoing enumeration of the rights and focusing instead on the importance of the interest.¹⁹⁰ This holding, however, was narrowed the following term, when the Court held that although "property interests protected by procedural due process extend well beyond actual ownership of real estate, chattels, or money, . . . [and] liberty [interests extend] beyond the sort of formal constraints imposed by the criminal process,"¹⁹¹ the "range of interests protected by procedural due process is not infinite."¹⁹²

In *Paul v. Davis* the Court further narrowed the class of liberty interests, holding that "[liberty] interests attain . . . constitutional status by virtue of the fact that they have been initially recognized and protected by state law . . . [and due process is triggered] whenever the State seeks to remove or significantly alter that protected status."¹⁹³

bidding on government contracts or applying for federal employment, when the bar arises from charges concerning the reputation of the person or entity involved, implicates a liberty interest when the bar effectively forecloses future employment or contracting opportunities).

186. The Fifth Amendment guarantees that "[n]o person shall be . . . deprived of life, liberty, or property, without due process of law." U.S. CONST. amend. V. The Fourteenth Amendment states that "[n]o State shall . . . deprive any person of life, liberty, or property, without due process of law" U.S. CONST. amend. XIV, § 1.

187. 262 U.S. 390 (1922).

188. *Id.* at 399.

189. 402 U.S. 535 (1971).

190. *Id.* at 539.

191. *Board of Regents v. Roth*, 408 U.S. 564, 571-72 (1972).

192. *Id.* at 570.

193. *Paul v. Davis*, 424 U.S. 693, 710-11, *reh'g denied*, 425 U.S. 985 (1976). Compare *Owen v. City of Independence*, 445 U.S. 622, 633-34 n.13 (1980) (affirming lower court's holding that conduct damaging reputation in connection with loss of employment impli-

Under this reasoning, individuals deprived by state action of interests implicated by the Due Process Clause are not afforded due process procedural protections unless the state had previously granted the interests to them.¹⁹⁴

In a similar vein, the Court in *Bishop v. Wood*¹⁹⁵ applied a similar limitation to procedural due process protections for property interests, stating that "the sufficiency of the claim of entitlement must be decided by reference to state law Whether such a guarantee has been given can be determined only by an examination of the particular statute or ordinance in question."¹⁹⁶

Although at first blush *Paul* and *Bishop* appear to narrow liberty and property interests to those afforded by state law, as shown below a broader reading of the holdings more accurately reflects the intent of the *Paul* and *Bishop* Courts.

(a) Debarment Proceedings Implicate a Liberty Interest

Debarment is the most severe sanction available in a science misconduct proceeding. It deprives the subject of the right to contract.¹⁹⁷ Traditionally, the right of the individual to contract has been considered a liberty interest under the Fifth and Fourteenth Amendments.¹⁹⁸ However, under current case law, for a liberty interest to warrant procedural due process protections, the *Paul* standard¹⁹⁹ must be satisfied.

Dicta in *Paul* suggested that cases involving damage to reputation and loss of employment²⁰⁰ may trigger due process protections.²⁰¹

cates due process). The Court in *Paul* also held that "[t]here are other interests . . . protected not by [state law] but because they are guaranteed in . . . the Bill of Rights." *Id.* at 711 n.5. For criticisms of *Paul*, see Henry Paul Monaghan, *Of "Liberty" and "Property"*, 62 CORNELL L. REV. 405, 423-29 (1977); David L. Shapiro, *Mr. Justice Rehnquist: A Preliminary View*, 90 HARV. L. REV. 293, 322-38 (1976); Mark Tushnet, *The Constitutional Right to One's Good Name: An Examination of the Scholarship of Mr. Justice Rehnquist*, 64 KY. L.J. 753 (1976); Randolph J. Haines, Note, *Reputation, Stigma and Section 1983: The Lessons of Paul v. Davis*, 30 STAN. L. REV. 191 (1977).

194. See Monaghan, *supra* note 193, at 424-25.

195. 426 U.S. 341 (1976).

196. *Id.* at 344-45.

197. The Court has stated that this interest

embrace[s] the right of the citizen to be free in the enjoyment of all his faculties; to be free to sue them in all lawful ways; to live and work where he will; to earn his livelihood by any lawful calling; to pursue any livelihood or avocation, and for that purpose to enter into all contracts which may be proper, necessary and essential to his carrying out to a successful conclusion the purposes mentioned above.

Allgeyer v. Louisiana, 165 U.S. 578, 589 (1897).

198. *Meyer v. Nebraska*, 262 U.S. 390, 399 (1922).

199. *Paul*, 424 U.S. at 710-11; see *supra* text accompanying note 193.

200. In *Paul*, respondent alleged his due process rights were violated when, following an arrest for shoplifting, the police circulated a flyer of "active shoplifters" that included

The Court adopted this position in *Owen v. City of Independence*,²⁰² holding that due process protections were triggered when loss of reputation was combined with loss of employment.²⁰³ Since debarment entails both of these things, these holdings suggest that due process protections must be provided in scientific misconduct proceedings both that result in or could result in debarment sanctions.

(b) Lesser Sanctions May Also Implicate Liberty Interests and Should Also Be Afforded Due Process Protections

Whether due process protections are essential in misconduct proceedings when termination of employment from a state institution is a possible sanction depends on whether the employee has a "legitimate claim of entitlement to job tenure."²⁰⁴ Such a claim may result from rules or understandings that can be implicit or explicit—for example, by contract.²⁰⁵ When an employee can be terminated at will the Court has held that due process protections are not warranted for termination.²⁰⁶ Employment arrangements that feature an express or implied expectation of continued employment, however, carry due process protections when dismissal occurs, because a property interest is implicated.²⁰⁷ Therefore, termination of employment may trigger due process protections.

The question remains whether due process protections are required when sanctions fall short of debarment or termination of em-

respondent's name and photograph. *Paul*, 424 U.S. at 695. The defamed respondent in *Paul* was not fired when the besmirching flyer came to the attention of the respondent's supervisor. *Id.* at 696.

201. The *Paul* Court stated that it has recognized the serious damage that could be inflicted by branding a government employee as "disloyal," and thereby stigmatizing his good name. But the Court has never held that the mere defamation of an individual, whether by branding him disloyal or otherwise, was sufficient to invoke the guarantees of procedural due process *absent an accompanying loss of government employment*. *Id.* at 706 (emphasis added).

202. 445 U.S. 622 (1980).

203. *Id.* at 633 n.13.

204. *Perry v. Sinderman*, 408 U.S. 593, 602 (1972).

205. *Id.*

206. In *Board of Regents v. Roth*, 408 U.S. 564 (1972), the Court held there was no property interest in employment when the contract was of finite duration and no provision was made for renewal. *Id.* at 578.

207. *Perry*, 408 U.S. at 599-600 (stating that de facto tenure based on mutual expectation of continued employment triggers due process); *see also Newman v. Burgin*, 930 F.2d 955, 959-61 (1st Cir. 1991) (suggesting that due process protections will be triggered when an individual accused of academic misconduct is also removed from former positions on administrative committees). *But see Bishop v. Wood*, 426 U.S. 341, 345 (1976) (holding that employment arrangements requiring only a statement of reasons prior to termination did not merit due process protections).

ployment secured by a just cause provision. Even if a person found guilty of wrongdoing receives only a simple reprimand, her reputation is damaged. However, as held by the Court in *Paul*, loss of reputation alone is not enough to trigger due process protections.²⁰⁸ Despite the Court's previous statement in *Wisconsin v. Constantineau*²⁰⁹ that "[w]here a person's good name, reputation, honor, or integrity is at stake because of what the government is doing to him, notice and an opportunity to be heard are essential,"²¹⁰ the Court distinguished *Constantineau* from *Paul* by observing that

the governmental action taken in [*Constantineau*] deprived the individual of a right previously held under state law—the right to purchase or obtain liquor in common with the rest of the citizenry. . . . It was that alteration of legal status which, combined with the injury resulting from the defamation, justified the invocation of procedural safeguards.²¹¹

If there is damage to reputation, without more, *Paul* establishes that the interest "is simply one of a number which the State may protect against injury by virtue of its tort law."²¹²

The case of loss of reputation by a scientist is not, however, a loss without more. When a scientist is reprimanded, she stands to lose not only her reputation, but also her opportunities for future employment. Lower courts have ruled in the wake of *Paul* that liberty interests are implicated when "loss of future employment opportunities coupled with . . . stigma . . . amounts to a foreclosure of opportunities,"²¹³ or when denial of the right to contract is based on lack of "integrity."²¹⁴

208. *Paul*, 424 U.S. at 701.

209. 400 U.S. 433 (1971).

210. *Id.* at 437; see also *Wieman v. Updegraff*, 344 U.S. 183, 191 (1952) (holding that constitutional protection is triggered when state action places "a badge of infamy" on citizen); *Joint Anti-Fascist Refugee Comm. v. McGrath*, 341 U.S. 123, 168 (1951) (Frankfurter, J., concurring) ("[T]he right to be heard before being condemned to suffer grievous loss of any kind, even though it may not involve the stigma and hardships of a criminal conviction, is a principle basic to our society.").

211. *Paul*, 424 U.S. at 708-09.

212. *Id.* at 712.

213. *Lawler*, 605 F.2d at 959 (emphasis added).

214. *Old Dominion*, 631 F.2d at 963. Both *Old Dominion* and *Lawler* argue that their holdings are consistent with *Paul*, in which the Court stated:

While we have in a number of our prior cases pointed out the frequently drastic effect of the "stigma" which may result from defamation by the government in a variety of contexts, this line of cases does not establish the proposition that reputation alone, apart from some more tangible interest such as employment, is either "liberty" or "property" by itself sufficient to invoke the procedural protection of the Due Process Clause.

Paul, 424 U.S. at 701 (emphasis added); see also *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 543 (1985) ("While a fired worker may find employment elsewhere, doing so will take some time and is likely to be burdened by the questionable circumstances under which he left his previous job."); *McGrath*, 341 U.S. at 185 (Jackson, J., concurring) (stating

Given the intensely competitive nature of science funding, damage to reputation is constructive disbarment. This is because "scientific research depends on public funding to an unprecedented degree."²¹⁵ The Senate Committee on Labor and Human Resources addressed the critical role of governmental funds in science research:

The decade of the 1980s brought many exciting scientific advances. . . . Unfortunately, the 1980s also brought increasing challenges to our ability to take advantage of these new opportunities because of tightening budget constraints. Funding for NIH has increased each year, but the gains after taking account of inflation have been too small to permit adequate support of many key areas of research.

. . . In the latter half of the last decade, . . . the success rate [for funding new and competing grants] declined from 33% to 24%. . . . over 70% of researchers are left to try to find support for their projects elsewhere . . . *There is a danger that some researchers . . . may leave the field entirely if they are too discouraged about the prospect[] of receiving [NIH] grant support.*²¹⁶

In such a highly competitive funding environment, a scientist deemed guilty of misconduct will find it very difficult to obtain grants in the future.

There is an additional liberty interest identified by the Supreme Court that may be applicable in this context—the right "to acquire useful knowledge."²¹⁷ Commentators discussing this interest in connection with misconduct hearings argue that "any governmental action which has the effect of denying or impairing the constitutionally guaranteed freedom of inquiry enjoyed by scientists must be preceded by notice and an appropriate opportunity to be heard."²¹⁸

that due process is required before one may be labelled a fascist because "[t]o be deprived not only of present government employment but of future opportunity . . . certainly is no small injury when government employment so dominates the field of opportunity"); *United States v. Lovett*, 328 U.S. 303, 314 (1946) (holding that employees were entitled to procedural due process when "congressional action . . . stigmatized [the employees'] reputation and seriously impaired their chance to earn a living What is involved here is a congressional proscription of [these employees], prohibiting their ever holding a government job."). *But see* *Board of Regents v. Roth*, 408 U.S. 564, 575 (1972) (suggesting that not all loss of employment opportunities will trigger due process—"it stretches the concept too far to suggest that a person is deprived of 'liberty' when he simply is not rehired in one job but remains as free as before to seek another") (citing *Cafeteria & Restaurant Workers Union v. McElroy*, 367 U.S. 886, 895-96 (1961)); *Abbs v. Sullivan*, 963 F.2d 918, 927 (7th Cir. 1992) (arguing that loss of grants by a scientist did not "invade a legally protected interest [because] he can always go back to teaching neurology in the classroom").

215. Woolf, *Deception in Scientific Research*, *supra* note 73, at 68.

216. S. REP. NO. 459, 101st Cong., 2d Sess. 16 (1990) (emphasis added), *reprinted in* 1990 U.S.C.C.A.N. 4547, 4549-50; *see also supra* note 215.

217. *Meyer v. Nebraska*, 262 U.S. 390, 399 (1922).

218. Richard Delgado & David R. Millen, *God, Galileo, and Government: Toward Constitutional Protection for Scientific Inquiry*, 53 WASH. L. REV. 349, 396 (1978). *But see*

Deciding whether due process protections are warranted based on the likely outcomes of proceedings makes it necessary to attempt to predict the outcomes before investigations have even begun. To ensure fairness and promote efficiency, the best approach is to provide due process protection in *every* instance of alleged misconduct that merits investigation.

(2) *There Must Be State Action Before Due Process Protections Are Required*

There must be state action to invoke the provisions of the Due Process Clause.²¹⁹ When considering whether a private university receiving federal funding is subject to constitutional restraints, the District of Columbia Circuit Court of Appeals stated in *Greenya v. George Washington University*²²⁰ that "the mere receipt of government loans or funding by an otherwise private university is not sufficient involvement to trigger constitutional guarantees in the University's relations with its employees."²²¹ The court stated that constitutional restraints are appropriate only when "conditions become so . . . pervasive that the Government has become, in effect, a joint venturer in the recipient's enterprise."²²²

One commentator has cited *Greenya* as authority that "[c]onstitutional restraints do not . . . apply to private institutions . . . in their dealings with research employees simply because they receive grants from NSF or NIH."²²³ However, federal funding was not directly at issue in *Greenya*. The appellant in *Greenya* argued that he was entitled to due process because the private institution that employed him, George Washington University, received federal funds.²²⁴ The *Greenya* court rejected this argument, reasoning that the appellant maintained no contractual relations with the federal funding entity, nor did the federal funding entity have "anything whatsoever to do with the failure to renew the appellant's contract."²²⁵ Under these circumstances, the court held that the appellant lacked a sufficient nexus to the federal funding agency to merit due process.

Misconduct proceedings are, however, different from the appellant's situation in *Greenya*. As explained above, misconduct proceed-

John A. Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 S. CAL. L. REV. 1203, 1212-14 (1977) (arguing that it is unlikely the Court would recognize a liberty or property interest in the right to do research).

219. Jackson v. Metropolitan Edison Co., 419 U.S. 345, 349 (1974).

220. 512 F.2d 556 (D.C. Cir.), cert. denied, 423 U.S. 995 (1975).

221. *Id.* at 562 (emphasis added).

222. *Id.*

223. Andersen, *supra* note 52, at 141.

224. *Greenya*, 512 F.2d at 561-62.

225. *Id.* at 562.

ings place federal funding directly at issue. Furthermore, the federal entity determines the future status of funds, and scientists have a contractual relationship with the federal funding agencies. Thus, the very factors enunciated in *Greenya* for implicating state action establish a nexus in the case of scientists faced with a charge of misconduct. At least for debarment proceedings, therefore, private institutions ought to accord due process protections to the accused.

In summary, due process guarantees only apply to misconduct proceedings conducted by a state institution or involving federal funds that deprive the subject of a liberty or property interest expressly guaranteed by the Constitution or previously granted by the state.

B. How Much Process Is Due?

In *Cafeteria Workers v. McElroy*,²²⁶ the Supreme Court held that "[t]he Fifth Amendment does not require a trial-type hearing in every conceivable case of government impairment of private interest."²²⁷ In doing so, the Court noted that "consideration of what procedures due process may require under any given set of circumstances must begin with a determination of the precise nature of the government function involved as well as of the private interest that has been affected by governmental action."²²⁸

In *Goldberg v. Kelly*,²²⁹ the Court set forth the due process protections that are constitutionally required in proceedings adjudicating the termination of welfare benefits,²³⁰ holding that such a proceeding requires a pre-termination evidentiary hearing.²³¹ While "the pre-termination hearing need not take the form of a judicial or quasi-judicial trial,"²³² the hearing must include the following elements: (1) "timely and adequate notice detailing the reasons for a proposed termination";²³³ (2) "an effective opportunity to defend by confronting any

226. *Cafeteria & Restaurant Workers Union v. McElroy*, 367 U.S. 886 (1961).

227. *Id.* at 894. The Fifth Amendment is similar to the Fourteenth Amendment with regard to restraints imposed on the government. *Bowles v. Willingham*, 321 U.S. 503, 518 (1944).

228. *McElroy*, 367 U.S. at 895; *see also Morrissey v. Brewer*, 408 U.S. 471, 481 (1972) ("[D]ue process is flexible and calls for such procedural protections as the particular situation demands.").

229. 397 U.S. 254 (1970).

230. *See id.* at 264-71.

231. *Id.* at 261. *But see Inland Empire Dist. Council v. Millis*, 325 U.S. 697, 710 (1945) (holding that hearing is not required at initial stage of an administrative proceeding).

232. *Goldberg*, 397 U.S. at 266.

233. *Id.* at 267-68. Notice which satisfies due process must be "reasonably calculated, under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections." *Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306, 314 (1950); *see also Memphis Light, Gas & Water Div. v. Craft*, 436 U.S. 1, 14 (1978) (stating that "[t]he purpose of notice under the Due Process

adverse witnesses²³⁴ and by presenting . . . arguments and evidence orally”²³⁵; (3) the right of the recipient to retain counsel; (4) evidence that the finding of the decision maker in the proceeding “rest[s] solely on the legal rules and evidence adduced at the hearing”; (5) an “impartial decision maker”; and (6) a statement from the decision maker detailing “the reasons for his or her determination and indicat[ing] the evidence he or she relied on.”²³⁶

Decisions in the wake of *Goldberg* established that the due process requirement of pretermination hearings is not limited to situations involving the deprivation of vital necessities;²³⁷ however, the Court struggled to determine when a given procedure was appropriate. One approach was to look to the procedures provided by Congress. For instance, the plurality in *Arnett v. Kennedy*²³⁸ stated, “The employee’s statutorily defined right is not a guarantee against removal without cause in the abstract, but such a guarantee *as enforced by the procedures which Congress has designated for the determination of cause.*”²³⁹

To ascertain congressional intent for due process protections in misconduct proceedings, one commentator has looked to the standards set forth in the Health Care Quality Improvement Act (HCQIA) of 1986,²⁴⁰ which sets forth due process standards applicable to physicians in disciplinary proceedings.²⁴¹ The HCQIA provides

Clause is to apprise the affected individual of, and permit adequate preparation for, an impending ‘hearing’”).

234. The Court in *Goldberg* noted that “[i]n almost every setting where important decisions turn on questions of fact, due process requires an opportunity to confront and cross-examine adverse witnesses.” *Goldberg*, 397 U.S. at 269. The Court continued that this protection is “even more important where the evidence consists of the testimony of individuals whose memory might be faulty or who, in fact, might be perjurers or persons motivated by malice, vindictiveness, intolerance, prejudice, or jealousy.” *Id.* at 270 (quoting *Greene v. McElroy*, 360 U.S. 474, 496-97 (1959)).

235. *Id.* at 268. With regard to the suitability of written submissions in lieu of oral presentation, the Court held that “[p]articularly where credibility and veracity are at issue . . . written submissions are a wholly unsatisfactory basis for decision.” *Id.* at 269.

236. *Id.* at 271.

237. See *Fuentes v. Shevin*, 407 U.S. 67, 88-89 (1972); *Bell v. Burson*, 402 U.S. 535, 539 (1971).

238. 416 U.S. 134 (1974).

239. *Id.* at 152 (emphasis added); accord *Hannah v. Larche*, 363 U.S. 420, 430 (1960) (arguing that an important guideline for determining the procedural due process protections appropriate for action taken by a given administrative agency is “whether or not ‘the President or Congress, within their respective constitutional powers, specifically has decided that the imposed procedures are necessary and warranted and has authorized their use’”) (quoting *Greene v. McElroy*, 360 U.S. 474, 507 (1959)).

240. Pub. L. No. 99-660, § 412, 100 Stat. 3784, 3786-87 (codified at 42 U.S.C. § 11112(b) (1988)).

241. Barbara Mishkin, *Responding to Scientific Misconduct; Due Process and Prevention*, 260 JAMA 1932, 1935 (1988).

for (1) notice stating the charges, the underlying reasons for the charges, a summary of the rights in the hearing (if requested), and a list of witnesses expected to be called; (2) the right to a hearing, to be held not less than thirty days after the date of the notice; (3) an impartial decision maker; (4) the right to call, examine, and cross-examine witnesses, and to present relevant evidence; (5) the right to submit a written statement at the close of the hearing; and (6) the right to receive the written recommendation of the decision-making entity, including a statement of the basis for the decision.²⁴²

Although statutory procedures may be a useful guideline, the Supreme Court has made it clear that they do not establish the required standard of due process.²⁴³ Instead, the Court has used a balancing test, as articulated in *Mathews v. Eldridge*.²⁴⁴ The *Mathews* test considers three factors:

First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.²⁴⁵

When considering the first factor—the private interest affected—the Court has stated that when the proceedings are of an *accusatory nature*, as would be the case in misconduct proceedings, “rigorous protections” are required.²⁴⁶ The core of a misconduct proceeding is an allegation of wrongdoing. The individual interest is the protection of one's reputation and one's ability to continue scientific research.

A scientist risks losing her scientific reputation as a result of a finding of misconduct, and her future livelihood is threatened. Although the sanctions for misconduct range from a simple reprimand to disbarment from receiving federal funds,²⁴⁷ even mild sanctions place the professional reputation of the scientist in danger, since science places such a premium on trustworthy data.²⁴⁸ A finding of misconduct may effectively end the scientist's career, because scientists

242. *Id.*

243. *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 541 (1985) (“The right to due process ‘is conferred, not by legislative grace, but by constitutional guarantee.’”) (quoting *Arnett*, 416 U.S. at 167 (Powell, J., concurring in part and concurring in result in part)).

244. *Mathews v. Eldridge*, 424 U.S. 319 (1976).

245. *Id.* at 335; accord *Loudermill*, 470 U.S. at 542-45.

246. *Hannah*, 363 U.S. at 488 (Frankfurter, J., concurring in result) (“Were the [investigating entity] exercising an accusatory function . . . the rigorous protections relevant to criminal prosecutions might well be the controlling starting point for assessing the protection which the . . . [investigating entity's] procedure provides.”).

247. See *supra* text accompanying notes 138-140, 158.

248. See *supra* text accompanying notes 5-7.

rely on the integrity of their fellow scientists. Advances made by a single scientist are extensions of results obtained by multitudes of others, which were, in turn, extensions of results obtained by those who came before. In such a system, the reliability of each piece is critical. Researchers will be hesitant to endanger the basis for their conclusions by incorporating data gathered by a scientist whose regard for the truth has been called into question. Misconduct proceedings therefore satisfy the first prong of the balancing test.

The second factor, inherent risk of error, is plainly implicated by a science misconduct proceeding.²⁴⁹ The scientific issues that must be resolved are often highly technical. Furthermore, because scientific research often proceeds through solitary experimentation without formal structure, scientists' actions during the alleged course of misconduct can be difficult to reconstruct.

The errors are exacerbated by the fact that misconduct proceedings typically begin and often end at research institutions. Even if the research is funded by a federal agency with established guidelines for misconduct investigations, the agency (with the exception of the NIH, at least while the ORI interim regulations are in effect²⁵⁰) has the discretion to decline review and accept the institution's findings. The research institutions can also impose sanctions without a further hearing.²⁵¹ Yet research institute guidelines for conducting misconduct proceedings are inconsistently drafted and unevenly applied. Moreover, misconduct proceedings are still infrequent enough that at least at the smaller institutes, the faculty members will be confronting the novel issues presented for the first time.

One consideration in assigning weight to the risk of error inherent in the process is whether the proceeding is investigative or adjudicatory in nature.²⁵² In investigative proceedings the harm from error

249. In emphasizing the importance of this factor, the Court stated that the "procedural due process rules are shaped by the risk of error inherent in the truthfinding process as applied to the generality of cases." *Mathews*, 424 U.S. at 344; see also *Loudermill*, 470 U.S. at 548 (Marshall, J., concurring in part and concurring in the judgment) ("[T]he employee is entitled to an opportunity to test the strength of the evidence 'by confronting and cross-examining adverse witnesses and by presenting witnesses on his own behalf, whenever there are substantial disputes in testimonial evidence.'" (quoting *Arnett*, 416 U.S. at 214 (Marshall, J., dissenting)) (emphasis added).

250. See *supra* text accompanying notes 127-130.

251. The research institution guidelines, however, can provide otherwise. For examples of guidelines used by research institutions in this type of proceeding, see *supra* Part II.C.

252. *Hannah*, 363 U.S. at 440-41; see also *Coral Gables Convalescent Home, Inc. v. Richardson*, 340 F. Supp. 646, 650 (S.D. Fla. 1972) ("[A] fundamental operative principle in administrative law 'is that a person aggrieved by the action of a government agency has a constitutional right to a trial-type hearing on issues of adjudicative fact.'" (quoting Note, *Withdrawal of Public Welfare: The Right to a Prior Hearing*, 76 YALE L.J. 1234, 1237 (1967))).

is presumably less significant and fewer due process protections are warranted than in a proceeding culminating in an adjudication. However, misconduct proceedings often collapse these fact-finding and adjudicatory phases.²⁵³ Thus the importance of the second factor is the same whether considering the proper level of due process required for science misconduct inquiries, investigations, or adjudicatory hearings.

Thus, misconduct proceedings have an inherently high risk of error, satisfying the second prong of the *Mathews* test. Furthermore, this prong must be afforded due consideration regardless of whether it is an inquiry, an investigation, or a hearing on science misconduct.

The third *Mathews* factor considers the public interest in limiting the administrative and fiscal burdens imposed on the government as a result of having to provide evidentiary hearings. The costs are incurred in litigating the misconduct claims on behalf of federal agencies, conducting hearings, drafting guidelines, and maintaining entire administrative departments focused solely on these concerns. Offsetting these costs are the savings to be realized by reducing the incidence of misconduct. In science misconduct disputes, the government has a considerable stake in providing the full measure of due process as a means to discover the truth.²⁵⁴ The governmental interest in ensuring that scientific research is free from fraud cannot be overstated.

The case history of Dr. Gallo bears this out.²⁵⁵ Whether deliberate or not, the incorrect assertion that despite the fact that LAV and HTLV-3B were nearly identical they were unrelated misled researchers about the virus's mutation rate.²⁵⁶ This error, in turn, misdirected researchers trying to devise urgently needed strategies for treatment of AIDS. Furthermore, Dr. Montagnier, who actually isolated the first AIDS virus, lost the initial patent race. This award depended critically on an independent virus isolation.²⁵⁷ If the situation had not been corrected, Dr. Montagnier and the Pasteur Research Institute would have lost millions of dollars in intellectual property rights.²⁵⁸ The tragedy in this case was, however, even more serious. Dr. Montagnier had the superior blood test for detection of AIDS, and before this fact was recognized, at least twelve individuals contracted

253. The NAS Panel reported that "[m]any institutional policies and procedures for addressing misconduct in science do not specify . . . [the] distinction [between adjudication and investigation]." NAS PANEL, *supra* note 2, at 107.

254. See *Loudermill*, 470 U.S. at 543 ("[S]ome opportunity for the employee to present his side of the case is recurringly of obvious value in reaching an accurate decision.").

255. See *supra* text accompanying notes 27-42.

256. Crewdson, *Burden of Proof*, *supra* note 20.

257. *Id.*

258. Gallo and Montagnier now share royalties from the patent. *Id.*

AIDS from transfusions of blood mistakenly identified as AIDS-free by the Gallo test.²⁵⁹

Although few misconduct cases involve issues of such overwhelming importance to the public welfare as that of Dr. Gallo, medical research is the most common type of research implicated in misconduct allegations.²⁶⁰ Due process facilitates fact-finding. Failure to subject evidence to the most rigorous examination possible can not only cloud research that should be continued, but also bestow a false badge of legitimacy to fraudulent research—with potentially dangerous effects on research strategies and medical treatments.²⁶¹ The administrative and fiscal burdens to the government are not insignificant, but they are outweighed by the interest in providing hearings.

IV. A Model Proposal for Science Misconduct Proceedings

Perhaps no part of the debate over treatment of alleged cases of misconduct rages more fiercely than who should handle allegations. Should it be the institutions themselves, or the funding agencies? Are there other alternatives? This issue is important, because it can have a profound impact on the fairness and efficiency of proceedings. This Note argues that the most appropriate venue for misconduct proceedings is not the research institution or the funding agency, but a distinct independent agency, established solely for the purpose of adjudicating charges of science misconduct.

Once this issue is resolved, characterizing the nature of the proceeding itself remains. The two most popular models for dealing with cases of alleged scientific misconduct are the “scientific dialogue” model and the “legal-adversarial” model.²⁶² The scientific dialogue model, followed by OSI, relies on the scientist to provide data to substantiate her claim.²⁶³ The former director and deputy director of the OSI, Jules V. Hallum and Suzanne W. Hadley, respectively, explain that “[t]he process is one of professional challenge to examine and

259. *Id.*

260. See Warren Schmaus, *An Analysis of Fraud and Misconduct in Science*, in AAAS-ABA CONFERENCE, *supra* note 3, at 87, 108 (reporting that 22 out of 25 reported cases of alleged misconduct in one study “were in some way connected with medicine”) [hereinafter Schmaus, *Analysis of Fraud*].

261. See Andersen, *supra* note 52, at 123 (stating that “[m]isconduct occurring during the course of research can adversely affect the public health and welfare. For example, misconduct in biotechnological research could result in releases of pathogenic organisms into the environment.”). Andersen also argues that “[b]ecause honesty is central to the scientific enterprise, misconduct places the future of science at risk.” *Id.* at 124.

262. Hallum & Hadley, *supra* note 110, at 650.

263. *Id.*

evaluate data rather than an accusation *per se*.”²⁶⁴ In defending the lack of opportunity to confront and cross-examine witnesses under this model,²⁶⁵ they state:

It is the issues of science identified by OSI that must be responded to and resolved. The respondent meets with OSI and is given the opportunity to rebut directly any *evidence* presented, with the advice of counsel, if desired. Thus there is a direct confrontation, *but of scientific issues*, not individuals.²⁶⁶

In contrast, the legal-adversarial model provides “trial-type” protections, including the right to confront and cross-examine witnesses.²⁶⁷ Hallum and Hadley caution that this approach is likely to reduce the involvement of scientists in these proceedings to that of “expert witnesses.”²⁶⁸

Underlying each of these two models is a fundamental question: Who is better suited to judge science misconduct—the scientist or the lawyer? How can a balance between science and law be achieved? This Note argues that the procedures followed should feature “trial-type” protections, with full opportunity for confrontation and cross-examination of witnesses, as well as observance of formal rules of evidence. Moreover, the findings of these hearings should be made by lawyers after judging the probative value of the facts presented in the context of the legal issues raised, rather than by scientists who evaluate the scientific evidence for merit.

A. The Venue Most Appropriate for Misconduct Hearings

The overwhelming sentiment among commentators on science misconduct is that the research institution is best situated to deal with issues of misconduct.²⁶⁹ One reason for this conclusion is that the alleged misconduct occurred there, and the individuals most likely to

264. *Id.* The authors contend that this model “functions in much the same spirit as does an editor of a scientific journal in dealing with problems in a submitted manuscript.” *Id.*

265. See *supra* text accompanying notes 113-126 for discussion of the procedures used in the OSI proceedings.

266. Hallum & Hadley, *supra* note 110, at 651 (emphasis added).

267. For an example of a proceeding based on this model, see *supra* text accompanying notes 128-134 (describing the interim procedures of ORI).

268. Hallum & Hadley, *supra* note 110, at 650.

269. See, e.g., Chalk, *supra* note 85, at 2 (stating that most of the participants at this multi-disciplinary conference “agreed that the universities should bear the primary responsibility and costs of investigating incidents of misconduct by their faculty, staff, or students”); NAS PANEL, *supra* note 2, at 122 (stating the Panel’s position: “[It] is important at this time to preserve institutional flexibility and discretion in developing and applying policies and procedures to address misconduct in science”); see also *supra* text accompanying notes 106-107, 141-145.

detect the misconduct are also there.²⁷⁰ Another frequently cited argument is that the research institution is in the best position to impose sanctions, because only the institution can terminate an employment contract.²⁷¹ Furthermore, since most allegations turn out to be misunderstandings or relatively minor matters, handling the investigation at the institutional level minimizes the impact of groundless charges.²⁷² Finally, the best way to minimize harm resulting from misconduct is by detecting it *before* it is published.

This type of self-policing nonetheless leaves much to be desired.²⁷³ Research institutions have come under attack for conducting inadequate investigations.²⁷⁴ Furthermore, questions of conflicts of interest often arise in this setting. One commentator, Harold Green, argues that institutions are "in a potential 'catch-22' situation."²⁷⁵ Confirmations that fraud has taken place suggest that the institution has used inadequate supervisory review and quality control; such a finding cannot help but damage the institution. However, failure to seek out the truth can be equally harmful. "If the research has been publicly funded, particularly if it is in some way politically sensitive, allegations of fraud could produce substantial political fallout."²⁷⁶

The case of Dr. Jeffrey Borer, a cardiologist accused of misconduct at Cornell University Medical School, is an excellent illustration of this. Dr. Borer was investigated in-house by Cornell University; however, Dr. Jerome Jacobstein, the whistleblower, became frustrated with the internal review procedures, and "sought to interest the University President's Office in the matter."²⁷⁷ The Cornell counsel "candidly asserted that his function was to represent the interests of the medical school."²⁷⁸ Green notes that "[i]t seems clear . . . the University's objective was to get rid of the problem as quickly as possible

270. Chalk, *supra* note 85, at 8; *see also* Andersen, *supra* note 52, at 135 (pointing out that the institution "usually has more direct and unfettered access to labs, witnesses, primary data, and other evidence").

271. Andersen, *supra* note 52, at 134.

272. *Id.* at 134-35.

273. For an excellent summary of the adequacy of the more recent university investigations that have been made public, see Mazur, *supra* note 44, at 183-90. Out of nine cases analyzed, the author felt only one case was handled adequately. *Id.* at 182. *But see* Floyd Bloom, *Who Should Police Scientific Misconduct*, 1 J. NIH RES. 14, 16 (1989) (arguing, in support of handling misconduct at the research institute level, that "[w]hereas cases involving whistle blowers make for dramatic media involvement, many other instances of error and misconduct get resolved more subtly within the system [T]hese corrections . . . allow[] almost all the involved parties to continue to work within the system for the good of that system.").

274. Mazur, *supra* note 44, at 182.

275. Green, *supra* note 55, at 1012.

276. *Id.*

277. *Id.* at 1023.

278. *Id.*

because Dr. Borer was a prominent researcher who attracted substantial funds to the University."²⁷⁹ This is a common danger with in-house investigations. Research grants are a tremendous source of university revenue, and such self-interest may taint the integrity of the review.²⁸⁰

Another disadvantage to siting misconduct proceedings at the universities is that whistleblowers, for the most part, will be more reluctant to raise their concerns at the university level. The individuals most likely to detect misconduct are those who are most familiar with the work—co-workers, colleagues, supervisors, and subordinates of the accused.²⁸¹ Yet it is at the research institute level that the whistleblower has the least chance of preserving her anonymity, and the most justification for fearing reprisal.

Some commentators have argued that journal peer review is the appropriate venue for screening misconduct.²⁸² They argue that scientific advancement depends on publication in scholarly journals. If the journals reject fraudulent papers, the impact of science misconduct is minimized. Furthermore, if fraudulent papers are published, the fraud will be discovered when other researchers attempt to duplicate the results.

These arguments are, however, suspect. First, fraudulent papers are not easily detected.²⁸³ Second, even when the errors should be easy to detect, journals do not have a good track record when it comes to detecting them.²⁸⁴ Another disadvantage of this approach comes

279. *Id.* The NIH, which was eventually brought into the Borer case, stated that Cornell's "'hasty conduct of the inquiry, and the failure to document the findings until later, created understandable doubts about the institution's willingness to deal with a potential problem.'" Memorandum from Associate Director for Extramural Affairs, Office of Extramural Research, to Director of the National Institutes of Health 5, 9 (Sept. 17, 1987) (copy on file with U. MICH. J.L. REF.), *quoted in* Green, *supra* note 55, at 1025.

280. *See, e.g.,* Benjamin Weiser, *How Well Do University Researchers Police Themselves; A Case at Georgetown Raises the Question*, WASH. POST, Jan. 22, 1991, at Z10. The whistleblower in a case against a leading nutritionist at Georgetown reported that the chair of the investigating committee attempted to dissuade her from pursuing her complaint by asking her "if [she] fully understood the potential outcome of a fraud investigation—that if evidence of fraud were found that the University might be forced to return grant money." *Id.* at Z12. The whistleblower was also cautioned that she "needed to be aware that [the accused individual] was a member of the Scientific Fraud Committee, that the members were her friends and would 'rally around her.'" *Id.*

281. A survey on misconduct from 1980 to 1987 revealed that co-workers were the primary source of science misconduct detection. Woolf, *Deception in Scientific Research*, *supra* note 73, at 64.

282. *See, e.g.,* *Hearings*, *supra* note 5. *Contra* Green, *supra* note 55, at 1012-15.

283. *See supra* note 78.

284. Two NIH scientists, Walter W. Stewart and Ned Feder, studied the errors in eighteen papers fabricated by Dr. John Darsee, a highly regarded clinical and experimental cardiologist who conducted research first at the Emory University School of Medicine and then at Harvard Medical School from 1978 to 1981. These investigators found that some

from the sheer number of scientific journals in existence.²⁸⁵ The task of implementing relatively uniform guidelines for verifying the data in submitted papers among these myriad journals is virtually insurmountable.

Another possible way to detect and expose fraud is through the various professional societies of scientists. The AAAS-ABA Conference reported that forty-six of a total of 146 scientific and engineering societies surveyed had adopted "some form of ethical rules" by 1980.²⁸⁶ Some commentators argue that because society members are more likely to be involved in the same area of research as the accused than fellow faculty members of a university with diverse specializations, professional societies may be better situated than universities to handle allegations of science misconduct.²⁸⁷

Professional societies, however, have a limited range of sanctions that they can impose after a finding of misconduct. They cannot withdraw federal funding or terminate employees. Sanctions by the professional societies would be confined to reprimands and withdrawals of society membership. As membership in professional societies is entirely discretionary, loss of membership may not be a significant deterrent. Another shortcoming to using professional societies as adjudicating bodies is that they may have difficulty maintaining the appearance of impartiality when scientists who have enjoyed years of prominence and influence in these societies are being investigated by their peers.²⁸⁸

errors were "so glaring as to offend common sense." Inspection of the family pedigree in Darsee's papers indicates that a 17-year-old male had children ranging in age from four to eight; his sister, brother, and first cousin had children at 16, 15, and 15, respectively; and three of the women in the preceding generation had children at ages 41, 45, and 52. Walter W. Stewart & Ned Feder, *The Integrity of the Scientific Literature*, 325 NATURE 207, 208 (1987).

285. Floyd Bloom points out that "[a]nyone who has ever served as a reviewer of grants or papers, or tried to arbitrate the contrasting interpretations of investigators, authors, and their reviewers, will recognize that peer commentary is not consistently wise, prudent, or constructive [T]he growth in the number of journals with new editors anxious to fill their pages regularly creates a demand for papers that almost ensures any report of publication somewhere. Furthermore, journal multiplication and the incessant flow of new data make keeping abreast of any field problematic" Bloom, *supra* note 273, at 16.

286. Chalk, *supra* note 85, at 35.

287. See, e.g., Schmaus, *supra* note 260, at 103. The participant concluded, however, that "funding agencies . . . may be in the best position to apply sanctions to scientists who are guilty of misconduct." *Id.* at 104; see also Andersen, *supra* note 52, at 121-22.

288. One participant in the AAAS-ABA Conference took the extraordinary position of suggesting that

when a scientist is charged with negligence, the fairest procedure would be one in which he or she is judged by other scientists in the same tradition of research. Membership in a research tradition could be determined by criteria such as the

Yet another approach is leaving the inquiries at the research institute level, and relying on the federal funding agencies to investigate. However, it is at the inquiry stage that research institutes have the most to gain by putting allegations to rest. When the inquiry proceeds to an investigation, the case becomes more visible, because even if newspapers have not been informed of allegations, more individuals are likely to become involved. As the case assumes a higher profile, the countervailing need to maintain an appearance of impartiality by continuing the investigation is enhanced. Hence, research institutes have the least to lose and the most to gain by stopping a misconduct probe at the inquiry stage. Therefore, they are not the most appropriate venue for the review of misconduct allegations.

Misconduct investigations should be conducted by an independent board established at the federal level. One authority in the field, Eugene Dong, proposes that responsibility for misconduct investigations should rest with the Department of Justice and the OIG of the DHHS.²⁸⁹ In order to have authority to withdraw federally granted funds, the board would need to be established under the auspices of the DHHS (with authority to debar the misconductee from PHS funds) or the NSF (with authority to debar the misconductee from NSF funds).²⁹⁰ Preferably, a board could be established under the joint auspices of the DHHS and the NSF (with the authority to debar the misconductee from PHS and NSF funds).

The board should be structured to deal with many of the concerns raised by advocates for university-based misconduct proceedings. Concerns that a nonuniversity venue might result in an increase in the number of groundless charges could be addressed by imposing penalties on whistleblowers who bring frivolous allegations, or who act out of malice. Any additional risk of undue exposure of the institute or the accused individual to unsubstantiated charges would be offset by the benefit gained through investigating meritorious but unreported claims. Instead of having to approach the individuals who wield considerable influence over her employment status and day-to-day working conditions, a whistleblower can go to an independent board that cannot retaliate against her.

The board would lack authority to terminate employment contracts; however, it could provide research institutions with a finding whether misconduct has occurred, based on an impartial evaluation of the charges raised. The research institute could then factor this find-

societies to which one belongs, the papers one cites, who one worked with in graduate school, who one's coauthors are, and so on.

Schmaus, *supra* note 260, at 98.

289. Eugene Dong, *Confronting Scientific Fraud*, CHRON. HIGHER EDUC., Oct. 9, 1991, at A52.

290. See *id.*

ing into its assessment of whether the individual found guilty of misconduct should be terminated. To insulate the research institution, the board should handle allegations of misconduct, from the initial inquiry through the final adjudication.

The recommendations set forth by the NAS Panel contain the seeds of this approach. The Panel proposed the establishment of an Independent Scientific Advisory Board, which would serve as a resource to "strengthen the processes and procedures used for handling and resolving allegations of misconduct in science."²⁹¹ These recommendations are a step in the right direction, but they do not go far enough to satisfy due process requirements. The board should be established at the federal level and have investigative as well as advisory duties.²⁹²

Notwithstanding the establishment of federal entities, research institutes need to establish committees to deal with allegations of misconduct involving research that is not federally funded. These committees must establish guidelines concerning questionable practices in science research, such as conventions for authorship and the form of data-keeping in the laboratory. These guidelines should be distributed to each research laboratory. At the discretion of the committee, a finding that a scientist failed to observe these guidelines could result, for example, in a evaluation of "poor performance" on the part of the violator, or could lead to more serious sanctions if warranted. However, the sanctions should not constitute a finding of "scientific misconduct." Misconduct guidelines should remain focused on the reduction of fraud. Sloppy research practices may make fraud harder to detect, but they do not rise to the level of misconduct and certainly do not justify threatening the career of an otherwise productive scientist.²⁹³

B. The Nature of the Proceeding

Proceedings to deal with misconduct should provide the full measure of due process protections. To this end, misconduct proceedings should be conducted in a setting designed to evaluate the facts underlying the charges raised. The adversarial process was designed for this purpose, and is the most appropriate means to discern the truth in allegations of misconduct.

The foundation of a fair misconduct proceeding is the establishment of a clear definition of "misconduct." Only fabrication, falsification, and plagiarism should be included in this category; however, far

291. NAS PANEL, *supra* note 2, at 124, 150. The board would also provide legal advice.

292. Eugene Dong's proposal for handling allegations of misconduct parallels this view. Dong, *supra* note 289.

293. See *supra* text accompanying note 60, and notes 67-68.

greater detail must be provided about what these terms mean than is provided in the PHS and NSF guidelines. The inclusion of "serious deviation from accepted conduct" category, as in the NSF and PHS regulations,²⁹⁴ does not provide sufficient guidance to the scientist about what conduct is acceptable, and may have a chilling effect on research.

The definition of misconduct proposed here incorporates many of the practices enumerated by the DHHS as actionable under the "serious deviation from accepted conduct" category.²⁹⁵ "Misuses by a journal referee or privileged information contained in a manuscript," "unauthorized use of data from another investigator's laboratory," and "failure to acknowledge that data used in a grant application were developed by another scientist" are plagiarism. If a scientist misrepresents the publication status of manuscripts on her curriculum vitae, or if she misrepresents the status of her research progress to the granting agency, she is "fabricating." A scientist is guilty of falsification if she alters the status of subjects in clinical research studies, selectively reports primary data, or uses improper statistical methodology in analyzing primary data. One practice not covered by fabrication, falsification, and plagiarism is the failure to maintain adequate records. Given the importance of scientific notebooks in establishing the facts in misconduct investigations, a minimum level of record keeping must be required. For example, primary data for publications could be maintained for a minimum of five years. Failure to observe these minima could be a factor in determining the accused's intent to defraud.²⁹⁶

The definition of misconduct should specify the level of scienter necessary for a determination of misconduct. The definition must require a showing of more than mere negligence and take into account both the inherent problems of self-deception in scientific research²⁹⁷ and the possibility of deterring creative research that does not always conform to slow, careful laboratory procedures. The appropriate level of culpability must be proportionate to actual intent to defraud, falsify, or plagiarize. This intent could be inferred when a scientist's recklessness manifests extreme disregard for the truth.²⁹⁸ A written statement outlining proscribed activities should be given to every researcher (not just principal investigators) actively involved in federally funded projects. These guidelines should also cover the role of

294. See *supra* text accompanying notes 53 and 55.

295. See *supra* text accompanying notes 66-67.

296. See *infra* text accompanying notes 297-298.

297. See *supra* text accompanying note 60, and note 92.

298. See Barbara Mishkin, *Due Process in Dealing with Scientific Misconduct*, in AAAS-ABA CONFERENCE, *supra* note 3, at 117, 126 (suggesting that the standard of proof should be "clear and convincing evidence").

whistleblowers, detail the responsibility to report fraudulent research, outline the protections provided for whistleblowers, and list the sanctions for groundless allegations.

The misconduct hearings should provide the full range of due process protections as outlined by the Supreme Court in *Goldberg v. Kelly*.²⁹⁹ The accused should be afforded notice, the right to counsel, the opportunity to confront and cross-examine witnesses, and to present her arguments and evidence orally.³⁰⁰ The interim proceedings set forth by ORI provide these protections.³⁰¹ However, given the complexity of the subject matter in misconduct allegations and the critical role intent plays in resolving them, formal evidentiary rules must also be followed in the proceedings.

Whether to use a scientific dialogue model or a legal-adversarial model for these proceedings is at heart a question of which approach affords the greatest protection to the accused, to the accuser, and to the public at large. The scientific dialogue model is attractive because it places the controversy in the hands of those who are most capable of untangling the scientific evidence to expose fraudulent practices—the scientists. The issues in misconduct cases are highly technical, but is scientific expertise required for the entire process? Scientific experts could explain to lay persons, for example, that a claim that a virus could not be cultured is refuted by evidence that the virus was in fact continuously cultured for several months. Legal proceedings often involve highly technical matters. However, even if the scientific dialogue method were better suited to resolve the scientific issues, it would be inappropriate because it does not provide due process protections. The legal-adversarial model resolves issues of fact.³⁰² Evidentiary rules are specifically directed to this purpose, as well as towards providing the accused with due process.

Despite Hallum and Hadley's argument to the contrary,³⁰³ the dispute in a misconduct case does not center around the scientific evidence. Rather, the intent of the accused to defraud, fabricate, or plagiarize is at issue. Intent is a legal, not a scientific, issue, and the adversarial process is designed to deal with legal issues. Intent is ultimately dispositive in resolving the case of whether Dr. Gallo, for ex-

299. 397 U.S. 254 (1970).

300. See *id.* at 267-69.

301. ORI Hearings at 53,125.

302. Eugene Dong asserts that "[t]here is no evidence that a knowledgeable scientific investigator is in any position at all to conduct an investigation into knowing misrepresentations of data." Dong, *supra* note 289. Dong argues that "scientists are properly used as expert witnesses in resolving disputed facts." *Id.* But see Woolf, *Deception in Scientific Research*, *supra* note 73, at 70-72 (arguing that scientists are better trained to judge the truth of scientific data than lawyers).

303. See *supra* text accompanying note 266.

ample, is guilty of misconduct. It is no longer disputed whether the virus in Dr. Gallo's paper was the one discovered by Dr. Montagnier—what is disputed is whether Dr. Gallo intended to claim the virus as his own.

Up to this point, the scientific dialogue model has been used to determine Dr. Gallo's guilt or innocence. The lack of a formalized evidentiary proceeding that might have resulted in a final determination of the facts has kept his name in the papers for six years. Similarly, Dr. Baltimore, who was also evaluated according to the scientific dialogue model, was subjected to a lengthy series of proceedings with conflicting outcomes, stretching out over years. Even though he was finally found innocent of misconduct, the damage to his reputation cost him his job. In the end, trying to resolve it quietly led to years of anguish.

Conclusion

Science misconduct is a problem in the scientific community. It must be addressed so that the public's faith in the results of scientific research can be preserved. However, not only the public is at risk if an adequate solution to the problem is not forthcoming. Scientists must trust the accuracy of research that precedes them. The scientific community and the federal funding agencies are beginning to take misconduct issues seriously. Their resolve must be accompanied by implementation of procedures that not only provide the full measure of due process protections to the accused, but also maximize the fact-finding potential of science misconduct proceedings. Creating an independent review board that uses the legal adversarial system gets us closest to attaining both of these goals.